Supreme Court, U.S.
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No. _____

In the

# Supreme Court of the United States

VALER V. SECAREA, JR.,
Plaintiff, Appellant and Petitioner

v.

REGENTS OF THE UNIVERSITY
OF CALIFORNIA,
KALYANAM SHIVKUMAR, M.D.,
DAVID CESARIO, M.D.,
CHARLES SWERDLOW, M.D.,
Defendants and Respondents

**PETITION FOR WRIT OF CERTIORARI**
**VOLUME 2 OF 2 APPENDIX B**

After a Decision by the California Court of Appeal,
Fourth Appellate District, Division Three

Valer V. Secarea, Jr.
12 Amberwicke
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In Propria Persona

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# The Second Amended Complaint

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**[Second Amended Complaint: Page 1; 1.CT.74]**

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**SUPERIOR COURT
OF THE STATE OF CALIFORNIA
FOR THE COUNTY OF ORANGE,
CENTRAL JUSTICE CENTER**

| | |
|---|---|
| VALER V. SECAREA, JR., individually and as Successor In Interest to NADINE F. SECAREA, decedent, | CASE NO.: 05CC10019<br><br>*Hon. William Monroe*<br>*Department C11*<br><br>SECOND AMENDED COMPLAINT FOR DAMAGES |
| Plaintiff, | 1. Wrongful Death |
| vs. | 2-3. Survival Action for Lack of Informed Consent |
| REGENTS OF THE UNIVERSITY OF | 4-5. Survival Action for Battery |

| | | |
|---|---|---|
| CALIFORNIA; CHARLES SWERDLOW, M.D.; KALYANAM SHIVKUMAR, M.D.; DAVID CESARIO, M.D.; IRVINE REGIONAL HOSPITAL AND MEDICAL CENTER, a business organization form unknown; RICK SWARTZENTRUBER, M.D.; ALLEN SCHWARTZ, M.D.; VITAL SIGNS, INC.; and DOES 1 through 350, inclusive,<br><br>Defendants. | ) | 6-7. Survival and Individual Action for Fraud<br><br>8. Survival Action for Negligence Per Se<br><br>9. Survival Action for Product Liability - Negligence<br><br>10. Survival Action for Strict Products Liability<br><br>11. Survival Action - *CCP* §377.20 |

**[Second Amended Complaint: Page 2; 1.CT.75]**

Comes now Plaintiff, VALER V. SECAREA, JR., individually and as successor in interest to NADINE F. SECAREA, decedent (hereinafter referred to as "NADINE"), submits this complaint for damages against defendants named herein and alleges as follows:

**Parties**

1. The true names and capacities of the defendants, DOES 1 through 350, inclusive, whether individual, corporate, associates or otherwise, are unknown to Plaintiff at the time of the filing of this Complaint and Plaintiff, therefore, sues said defendant, and each of them, by such fictitious names and capacities and will ask leave of court to amend this complaint to show their true names or capacities when the same have been ascertained. Plaintiff is informed and believes, and therefore alleges, that each of the DOE defendants is, in some manner, responsible for the events and happenings herein set forth and proximately caused injury and damages to the Plaintiff as herein alleged.

2. At all times herein mentioned, each of the defendants was the agent and employee of each of the remaining defendants and was at all times herein mentioned acting within the scope of said agency and employment.

3. At all times herein mentioned, defendant REGENTS OF THE UNIVERSITY OF CALIFORNIA,

a public entity, and DOES 1 through 25, inclusive, own and control all University of California campuses, including the University of California at Los Angeles and the University of California, Los Angeles Medical Center (hereinafter referred to as "UCLA").

4. At all times herein mentioned, defendant CHARLES SWERDLOW, M.D., and DOES 26 through 50, inclusive (hereinafter referred to as "Dr. Swerdlow") was, and is, a physician duly licensed to practice medicine, and actively practicing medicine, in the County of Los Angeles, State of California.

5. At all times herein mentioned, defendant KALYANAM SHIVKUMAR, M.D. and DOES 51 through 100, inclusive (hereinafter referred to as "Dr. Shivkumar") was, and is, a physician duly licensed to practice medicine, and actively practicing medicine, in the County of Los Angeles, State of California.

**[Second Amended Complaint: Page 3; 1.CT.76]**

6. At all times herein mentioned, defendant DAVID CESARIO, M.D. and DOES 101 through 150, inclusive (hereinafter referred to as "Dr. Cesario") was, and is, a physician duly licensed to practice medicine, and actively practicing medicine, in the County of Los Angeles, State of California.

7. At all times mentioned UCLA Defendants refers collectively to "UCLA," "Dr. Swerdlow," "Dr. Shivkumar," and "Dr. Cesario."

8. At all times mentioned UCLA Doctors refers collectively to "Dr. Swerdlow," "Dr. Shivkumar,"

and "Dr. Cesario."

9. At all times herein mentioned, defendant IRVINE REGIONAL HOSPITAL AND MEDICAL CENTER, a business organization form unknown, and DOES 151 through 200, inclusive (hereinafter referred to as "Irvine Regional") was, and is, a business organization authorized to do, and actively doing, business in the County of Orange, State of California.

10. At all times herein mentioned, defendant RICK SWARTZENTRUBER, M.D. and DOES 201 through 250, inclusive (hereinafter referred to as "Dr. Swartzentruber") was, and is, a physician duly licensed to practice medicine, and actively practicing medicine, in the County of Orange, State of California.

11. At all times herein mentioned, defendant ALLEN SCHWARTZ, M.D. and DOES 251 through 300, inclusive (hereinafter referred to as "Dr. Schwartz") was, and is, a physician duly licensed to practice medicine, and actively practicing medicine, in the County of Orange, State of California.

12. Plaintiff is uncertain as to the true names and status of defendant VITAL SIGNS, INC., and DOES 301 through 350, inclusive (hereinafter referred to as "Vital Signs"), or whether defendant is a corporation, general partnership, limited partnership, unincorporated association, or otherwise. Plaintiff is informed and believes, and thereon alleges, that said defendant, Vital Signs is duly licensed to do business, was and is doing business, under and by virtue of the laws of the State of California, and in the County of Los Angeles, including, but not limited to designing,

manufacturing, making, producing, promoting, selling, distributing, advertising, and supplying of the Esophageal Stethoscope with Temperature Sensor, Model 1101 18 Fr

**[Second Amended Complaint: Page 4; 1.CT.77]**

Stethoscope, 400 series, sold under the trade name of Vital Temp Monitoring Device (hereinafter referring to the device as the "Vital Signs Probe," "Vital Signs Device", "Vital Temp Probe" and/or "anaesthesiologist's temperature probe" ).

13. Plaintiff is informed and believes, and thereon alleges, that said defendant Vital Signs is duly licensed to do business, were and are doing business, under and by virtue of the laws of the State of California, and in the County of Los Angeles, including, but not limited to designing, manufacturing, making, producing, promoting, selling, distributing, advertising, and supplying of Vital Temp Probe sold under the trade name of Vital Temp Monitoring Devices.

14. At all times relevant hereto, Plaintiff was, and is, the legal husband, surviving heir and successor in interest of the decedent, NADINE F. SECAREA and her estate.

## General Allegations
## Overview of Circumstances [1]

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[1] Given this document's length, and so that it is more convenient to cross-reference the many complex issues, footnotes provide a reference the sections which explain the details of allegations made in a broader context – such as this introduction.

15. The untimely death of NADINE F. SECAREA was determined by the Orange County Sheriff-Coroner to be caused by "Anoxic/ischemic encephalopathy," due to "Esophago-left atrial fistula," due to "Complication of radiofrequency catheter ablative therapy for atrial fibrillation, clinical." [2]

16. This complaint alleges that the course of events which led to NADINE's unnecessary and premature death was caused by an experimental form of the ablation procedure, which put NADINE gratuitously in harm's way, in the interest of pure medical research,[3] [4] and that was surreptitiously performed by a "ghost surgeon" [5] and that none of these things was known to or consented to by NADINE, or Plaintiff, her husband, to whom the duty of informed

**[Second Amended Complaint: Page 5; 1.CT.78]**

consent passed, during the times when NADINE was unconscious or incapacitated and was unable to speak

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[2] Letter dated 20 December 2004, to Plaintiff, from Orange County Sheriff-Coroner.

[3] See *The Experimental Form of the Ablation Procedure Revealed*, at page 40, *infra*.

[4] See *Experimental Ablation Gratuitously Put NADINE "In Harm's Way,"* at page 54, *infra*.

[5] See *Training Dr. Cesario at the Expense of NADINE's Life*, at page 56, *infra*.

for herself.

17. Moreover, as a matter of public policy, the experimental form of the ablation procedure could NOT be considered consented to by NADINE, because it embodied blatant violations of statutory provisions which were enacted specifically to protect the public, including NADINE, from the very harm that befell her. In particular, (1) the experimental form of the ablation procedure employed a medical device, used in a medical research context, which required FDA clearance prior to its being tested on human patients,[6] and (2) before NADINE could be subjected to the experimental form of the ablation procedure, her informed consent was a mandatory requirement of not only statutory provisions,[7] [8] but of policies and regulations established by the Regents of the University of California and UCLA regarding protection of human subjects in medical research,[9] which themselves have the force of law, because of the University of California's status as

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[6] See *FDA IDE Approval Required for Medical Device Research*, at page 17, *infra*.

[7] See *Use of the New Device Required NADINE'S Informed Consent*, at page 21, *infra*.

[8] See *II. California Health and Safety Code § 24170, et. seq.*, at page 22, *infra*

[9] See *III. Policies Enacted by the Regents of the University of California for the Protection of Human Subjects in Medical Experimentation on All Campuses*, at page 24 and *IV. Policies Enacted by UCLA for the Protection of Human Subjects in Medical Experimentation*, at page 30, *infra*.

an independent agency of government.

18. In addition, NADINE's physicians and Irvine Regional, where NADINE was transported as soon as symptoms of the atrio-esophageal fistula appeared, failed to assemble the information and data needed to correctly diagnose and treat NADINE's critical condition.

19. Lastly, medical instrument maker, Vital Signs, failed in its duties under the doctrine of strict products liability, thus contributing to NADINE's predicament. Vital Signs withheld from the marketplace, critical information about the Vital Temp Probe's performance specifications and limitations, essential to avoiding and/or preventing its misuse.

20. Under the circumstances as are detailed infra, the ablation procedure to which NADINE had actually consented was NOT performed. It was the addition of a surreptitious and

**[Second Amended Complaint: Page 6; 1.CT.79]**

recklessly conceived experimental component, to NADINE's cardiac catheter ablation procedure, as well as the addition of "on-the-job training" for an unknown unconsented to understudy, which transformed it from generally safe and effective to precarious and unpredictable, and subjected NADINE to an entirely undisclosed, unknown, unanticipated, unconsented to

and unlawful [10] course of conduct which was so far beyond her objectively reasonable expectations that her consent to surgery was vitiated and annulled.

21. Had Drs. Swerdlow and Shivkumar performed the ablation procedure they promised NADINE and Plaintiff, she would be alive and well today, and Plaintiff would not be writing this account.

**General Allegations - Facts**

22. At times and/or during periods of the time herein mentioned, certain defendants, and each of them, consulted and collaborated with one another either directly or indirectly, expressly or implicitly, resulting in a unity of action in relation to this matter. Plaintiff does not now know the identity of each person or entity or the true extent of such collaboration, but pleads cumulatively the causes appearing herein, and will ask leave of the court to amend this complaint to show the true names of the collaborators and nature of said collaboration when the true character of said actions have been ascertained.

23. At all times herein mentioned, the conjunctive form "Plaintiff and NADINE" or "NADINE and Plaintiff" is intended to show the close cooperation and partnership between husband and wife in this matter, and in their common interest in protecting the physical safety and broad interests of their marital

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[10] See *Protection of Human Subjects in E xperimentation*, beginning at page 11, *infra*.

union and one another, and not necessarily an indication of persons to whom a legal duty is owed. At all times it is presumed that the legal duty of doctors and hospitals was owed to NADINE until such time she was incapacitated or was unable to speak for herself and/or until Plaintiff became her successor in interest.

24. At all times herein mentioned when NADINE was under anesthesia at UCLA,

**[Second Amended Complaint: Page 7; 1.CT.80]**

she was incapacitated and was unable to speak for herself.

25. At all times herein mentioned while NADINE was in the EP Lab, UCLA medical personnel had asked for and obtained Plaintiff's cell phone number so that he could be contacted, if necessary, should a situation arise regarding NADINE's ablation treatment.

26. At all times herein mentioned NADINE and Plaintiff jointly participated in the process of interviewing and querying Drs. Swerdlow and Shivkumar regarding proposed treatment for NADINE's cardiac arrhythmia. Their purpose was to work together hearing and reviewing information given them so that no detail of NADINE's care should be overlooked and NADINE would have a safe and effective surgery. During these times Drs. Swerdlow and Shivkumar made representations to NADINE and Plaintiff which they jointly assessed in arriving at the decision that NADINE should have the catheter ablation procedure performed by Drs. Swerdlow and Shivkumar at UCLA. Drs.

Swerdlow and Shivkumar were informed by NADINE that the spouses were making this medical decision jointly.[11] Neither Dr. Swerdlow or Dr. Shivkumar objected to any question directed at either of them by NADINE or Plaintiff, individually or jointly. Drs. Swerdlow and Shivkumar *voluntarily assumed the duty* to both NADINE and Plaintiff of candid, complete and truthful disclosure on the matters which affected NADINE's consent to treatment.

27. At all times herein mentioned, "electrophysiologist" refers to a medical specialist whose practice area is devoted to the treatment of cardiac arrhythmia.

28. At all times herein mentioned, "electrophysiology laboratory," or "EP Lab," refers to an enclosed area especially instrumented for the purpose of performing cardiac catheter ablations. An EP Lab is to an ablation procedure what an operating room is to open heart surgery.

29. At all times herein mentioned, "ablation procedure" refers to a cardiac catheter ablation procedure for treating atrial tachycardia..

30. At all times herein mentioned, "experimental ablation procedure," "experimental form of the ablation procedure," refers to an ablation procedure employing an untested,

**[Second Amended Complaint: Page 8; 1.CT.81]**

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[11] See *NADINE Selects Her Surgical Team*, at page 30, *infra*.

unproven technique devised by Drs. Cesario, Shivkumar and Swerdlow, et. al., which *theorizes* that temperature measurements made from within the esophagus with an anaesthesiologist's temperature probe, during a catheter ablation, supplies sufficient information and indication to avoid the kind of thermal injury to the esophagus that was the cause of NADINE's death.[12]

31. The ablation procedure which was performed on NADINE on 11 August 2004 at UCLA Medical Center was experimental and investigational in nature because, inter alia, (1) it contained an undisclosed "experimental component" which was being tried, for the first time, not for NADINE's benefit as an individual, but on a series of human patient-subjects, including NADINE, without any prior evaluation and approval by the UCLA IRB [13] as to its scientific basis, safety and effectiveness, (2) the experimental component relied on untested, unverified, and unproven speculation and conjecture devised by Drs. Cesario, Shivkumar and Swerdlow, et. al., which required

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[12] See *The Experimental Form of the Ablation Procedure Revealed*, at page 40, *infra*.

[13] "The Institutional Review Boards (IRBs) at UCLA commonly referred to as the HSPCs (Human Subject Protection Committees), are required by federal regulations to review all University affiliated human subject research, regardless of funding, to ensure the rights, welfare, and protection of all subjects." (See the UCLA *Investigator's Manual on Research with Human Subjects*, page 1-2.)

NADINE's informed consent, [14] [15] [16] [17] and (3) the experimental component relied on the untested and unverified performance of a medical device, the Vital Signs Probe, which was used, not in the practice of medicine, but in an investigational and experimental context, without FDA approval or certification.[18]

32. At all times herein mentioned, the addition of an experimental component, to the standard ablation procedure transformed it from generally safe and effective to precarious and

**[Second Amended Complaint: Page 9; 1.CT.82]**

unpredictable, and subjected NADINE to an entirely undisclosed, unknown, unanticipated, unconsented to and unlawful course of conduct which was so far beyond NADINE's objectively reasonable expectations and informed consent that it vitiated and annulled her

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[14] See *Use of the New Device Required NADINE'S Informed Consent*, at page 21, *supra*..

[15] See *II. California Health and Safety Code § 24170, et. seq.*, at page 22, *infra*.

[16] See *III. Policies Enacted by the Regents of the University of California for the Protection of Human Subjects in Medical Experimentation on All Campuses*, at page 24, *infra*,

[17] *See IV. Policies Enacted by UCLA for the Protection of Human Subjects in Medical Experimentation*, at page 30, *infra*.

[18] See *UCLA Doctors Were Engaged in an Investigation of a Medical Device*, at page 18.

consent to surgery.

33. At all times mentioned, UCLA Doctors concealed their academic and publishing interest in the experimental form of the ablation procedure from NADINE and Plaintiff.[19]

34. At all times herein mentioned, the heightened risks associated with undergoing the experimental form of the ablation procedure were never disclosed to NADINE or Plaintiff.[20]

35. At all times herein mentioned, the undisclosed academic and publishing interest of the UCLA Doctors in the experimental form of the ablation procedure unduly influenced and determined the course of NADINE's medical treatment, to her detriment.[21]

36. At all times herein mentioned, Drs. Cesario and Swedlow gratuitously ablated over NADINE's esophagus to accommodate their medical research efforts, thereby placing NADINE "in harms way" for no purpose which would legitimately benefit her as a patient.[22]

37. At all times herein mentioned, an experimental procedure conducted in the interest of

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[19] See *The Experimental Form of the Ablation Procedure Revealed*, at page 40, *infra*.

[20] See *Experimental Ablation Gratuitously Put NADINE "In Harm's Way,"* at page 54, *infra*.

[21] Ibid.

[22] Ibid.

medical research [23] requires the clear and unambiguous informed consent of the patient-subject because, inter alia, the conduct of a procedure to verify, test, validate or report clinical results, is controlled by the requirements imposed by law.

38. At all times herein mentioned, the experimental ablation procedure that was

**[Second Amended Complaint: Page 10; 1.CT.83]**

surreptitiously performed on NADINE was entirely alien to and beyond the scope of her objectively reasonable expectations and informed consent. [24] [25] [26] [27]

39. At all times herein mentioned, subjecting

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[23] The UCLA *Human Research Investigator's Manual*, at page 9-7, distinguishes the "practice of medicine" -- i.e., care of individual patients -- from "medical research" -- the intention of contributing to generalizable knowledge, or the contemplation of reporting results -- even as a collection or series of case studies. Thus, according to this definition, the experimental form of the ablation procedure, to which NADINE was surreptitiously subjected, is medical research, subject to statutory and regulatory controls and disclosures.

[24] See *The Interview With Dr. Swerdlow* at page 32, *infra*.

[25] See *The Interview with Dr. Shivkumar*, at page 35, *infra*.

[26] See *Dr. Shivkumar's "Good Hands" Promise*, at page 36, *infra*.

[27] See *The Pre-Surgical Consultation with Dr. Shivkumar at UCLA*, at page 37, *infra*.

NADINE to the experimental ablation procedure transformed her status from "patient" to "laboratory animal," killing her, and producing nothing of value -- all without her knowledge or consent.[28]

40. At all times herein mentioned, "conditional consent" refers to NADINE's consent to the ablation procedure conditioned on the requirement that it be personally performed by the surgical team of Drs. Charles Swerdlow and Dr. Kalyanam Shivkumar, and no one else.[29]

41. At all times herein mentioned, the abandonment of NADINE by her UCLA attending physician, Dr. Kalyanam Shivkumar, and the substitution of understudy Dr. Cesario constituted abandonment of NADINE by her surgical team and transformed NADINE's ablation procedure from medical treatment intended to benefit NADINE into "on-the-job training" intended to benefit understudy Dr. Cesario.[30] These actions were entirely alien to and beyond the scope of NADINE's objectively reasonable expectations and informed consent to the treatment procedure proposed by Drs. Swerdlow and Shivkumar to treat her cardiac arrhythmia.

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[28] See *Publication of "Less Than Entirely True" Research Results*, at page ?, *infra*.

[29] See *NADINE Selects Her Surgical Team*, at page 32, *infra*.

[30] See *Training Dr. Cesario at the Expense of Nadine's Life*, at page 56, *infra*.

**UCLA Medical Center's Dual Capacity Operations**

42. At all times herein mentioned, UCLA operated in the dual capacity of service provider and seller to the public of medical paraphernalia of almost every description.

43. Before NADINE and Plaintiff left UCLA the day of her discharge, Plaintiff

**[Second Amended Complaint: Page 11; 1.CT.84]**

purchased medications prescribed for NADINE at a sales outlet designated by UCLA as "the Pharmacy." Because it took the better part of an hour for Plaintiff to receive and pay for his order, Plaintiff was able to observe many members of the public as well as those identifiable as UCLA Medical Center personnel, obtaining medical paraphernalia of just about every description from this facility, located within the UCLA Medical Center complex.

**Protection of Human Subjects In Experimentation**

44. At all times herein mentioned, use of a medical device in an investigational setting as well as the experimental form of the ablation procedure *required* the informed consent of NADINE and other approvals on the part of Defendants under, *inter alia*, the

I. Federal Food, Drug and Cosmetic Act

(FDCA).

II. California Health & Safety Code, § 24170, et. seq., (Protection of Human Subjects in Medical Experimentation Act).

III. Policies enacted by the UC Regents for the protection of human subjects in medical experimentation (*UC Contract & Grant Manual* ).

IV. Policies enacted by UCLA for the protection of human subjects in medical experimentation (UCLA *Investigator's Manual for the Protection of Human Subjects*).

These statutes, regulations and policies were enacted to protect the public, including NADINE, from unauthorized, unconsented to and surreptitious medical research and experimentation.

45. The breaches of statutory duty, *supra*, are implicated by the experimental form of the ablation procedure which was performed on NADINE, because:

(1) a medical device, the Vital Signs Probe, was used in pursuit of medical research, the substance of which was to evaluate the ability of this device to be utilized for a new intended use as an "atrio-esophageal fistula condition diagnostic and prevention device," which is inconsistent with its FDA certified use as an "esophageal stethoscope/temperature probe." Therefore, it required the express approval from the FDA under the FDCA before it could be used experimentally in NADINE's and other patients' ablation procedures, AND

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(2) the experimental form of the ablation procedure had as its primary objective "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge" [31] and publication of experimental results.[32] This particular undertaking, as is explained, *infra*, required UCLA IRB approval as well as NADINE's informed consent under California Health & Safety Code, § 24170, *et. seq.*, (Protection of Human Subjects in Medical Experimentation Act), policies enacted by the UC Regents for the protection of human subjects in medical experimentation *(UC Contract & Grant Manual* ), and policies enacted by UCLA for the protection of human subjects in medical experimentation (UCLA *Investigator's Manual for the Protection of Human Subjects*).

46. The elements of legal duty applicable to these allegations are explained in the sections which follow.

47. Note that a rather complete description of the FDA medical device approval process is reviewed in order to keep its discussion in a proper framework, notwithstanding the fact that much of this process would not necessarily apply to the instant case.

I

**Federal Food, Drug, and Cosmetic Act ("FDCA")**

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[31] This is the definition of "research" as provided by 45 CFR 46.

[32] See *Publication of "Less Than Entirely True" Research Results*, at page 52, *infra*.

48. The United States Food and Drug Administration ("FDA") protects public health by approving and monitoring products for safety pursuant to the Federal Food, Drug and Cosmetics Act ("FDCA"), 21 USC § 301 et seq., and 21 CFR parts 800-97. In particular, the FDA evaluates medical devices for human use at the Center for Devices and Radiologic Health ("CDRH").

49. The experimental form of the ablation procedure was a research enterprise, according to Drs. Swerdlow and Shivkumar.[33] Moreover, the conversion of the Vital Signs Probe from its FDA certified intended use to an "atrio-esophageal fistula condition diagnostic and

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prevention device," (*New Device*) embraced a device study within the meaning of the FDCA. Indeed, the number of questions left open to inquiry by Drs. Swerdlow's and Shivkumar's experimental procedure mandated FDA approval of the device-related component of this research.[34]

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[33] See *The Experimental Form of the Ablation Procedure Revealed*, at page 40, *infra*.

[34] It should be noted that, although the broad review of FDA "new device" regulations which is presented *infra* usually applies to those whose activities involve manufacturing, remanufacturing or distribution, as is explained, it also applies with equal force to those involved in medical research, including universities, whether

## The *New Device* is a Medical Device Under 21 USC § 321(h)

50. The definition of medical device is broad and includes everything from toothbrushes to x-ray cameras. A medical device is defined under 21 USC § 321(h) as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is - (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them, (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (3) intended to affect the structure or any function of the body of man or other animals and which does not achieve its primary intended purpose through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes."

51. The New Device Defendant UCLA Doctors tested on NADINE in the experimental form of the ablation procedure, described infra, is a medical device as defined by 21 USC § 321(h), and would generally be subject to FDA regulation and controls.

## The New Device is a Class III Device

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or not that research is manufacturer-sponsored.

52. FDA groups medical devices into three different Classes [35], I, II or III according to 21 USC 360c, with Class III having the most stringent controls required prior to use. *All devices*

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*intended for use on humans are initially classified as Class III by operation of law*, according to 21 USC 360c(f)(1).

53. A new medical device always requires FDA clearance before being used on human patients. FDA clearance under the FDCA is either (1) automatically presumed for certain classes of medical device and uses or (2) requires express FDA approval. As will be explained infra, the *New Device* does not qualify for automatic clearance and no express approval was sought for test use of the *New Device* by UCLA or the UCLA Doctors.

## Three Paths to Obtaining FDA Device Investigation Clearance

54. In the usual course of events, there are three ways in which a new device attains FDA clearance for use on humans in the United States: (1) a Premarket notification or "501(k) certification, (2) a Premarket

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[35] See the "on-line" United States Department of Justice *Civil Resource Manual*, Section 110, Medical Device Law -- An Overview, at: http://www.usdoj.gov/usao/eousa/foia_reading_room/usam/title4/civ00110.htm.

Approval Application or "PMA," and (3) an Investigational Device Exemption or "IDE." Each is explained below, but only one is likely to be applicable under the facts of this case and it is the Investigational Device Exemption (IDE).

(1) Premarket Notification or 510(k) [36]

55. A 510(k) is named for the relevant provision of the FDCA, FDCA § 510(k), 21 U.S.C. § 360(k), and also known as a premarket notification or "PMN," is by far the more common of the two mechanisms. As compared to PMAs, 510(k)s are generally much shorter, reviewed more quickly, and, unlike PMAs, do not usually contain clinical data.

56. In "clearing" a 510(k), FDA makes a finding that the new device is "substantially equivalent" to a "predicate" device.

57. A "predicate" is a device that was legally marketed before May 28, 1976 (the effective date of the Medical Device Amendments of 1976) and that is not required to have a PMA, a device that has been classified into Class I or Class II (see below), or any device that is covered by a cleared 510(k). See FDCA § 513(f)(1), 21 U.S.C. § 360c(f)(1).

58. "Substantially equivalent" means that the new device has the same intended use and the same technological characteristics as the predicate device, or it has the same intended use

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[36] Ibid.

and different technological characteristics, but the information submitted in the 510(k) demonstrates that the new device is as safe and effective as the predicate and does not raise different questions regarding safety and effectiveness than the predicate. FDCA § 513(i)(1)(A), 21 U.S.C. § 360c(i)(1)(A); see also 21 C.F.R. § 807.100(b).

59. Under these circumstances, a *device must have the same intended use* as the predicate device, *as well as the same technological characteristics or demonstrated safety and effectiveness* in order to be "substantially equivalent" (21 USC § 360c(I)). [Emphasis added.].

(2) Premarket Approval Application or "PMA" [37]

60. A PMA is analogous to an NDA for a new drug. PMAs are far more complex than 510(k)s, because in order to obtain FDA approval of a PMA the sponsor must provide FDA with a reasonable assurance that the device is safe and effective for its intended use. FDCA § 515(d)(2), 21 U.S.C. § 360e(d)(2); see generally 21 C.F.R. part 814. A PMA will usually include the results of extensive clinical studies, and may be in the FDA review process for a period of years.

61. In approving a PMA, FDA can (and often does) impose conditions on a device or its manufacturer.

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[37] Ibid.

FDCA § 515(d)(1)(B)(ii), 21 U.S.C. § 360e(d)(1)(B)(ii); see also 21 C.F.R. § 814.82(a). For example, FDA may require that a device be restricted to prescription use. See FDCA §§ 515(d)(1)(B)(ii), 520(e), 21 U.S.C. §§ 360e(d)(1)(B)(ii), 360j(e). (Note that FDA can also impose restrictions on devices by means of a regulation. See FDCA § 520(e), 21 U.S.C. § 360j(e).)

(3) Investigational Device Exemption or "IDE." [38]

62. A clinical investigation involving a medical device will generally be conducted under an Investigational Device Exemption (IDE). An IDE, like its counterpart for drugs, the IND (Investigational New Drug), functions as an exemption from other provisions of the FDCA. See FDCA §§ 520(g), 505(i), 21 U.S.C. §§ 360j(g), 355(i). If a clinical investigation is being



conducted in accordance with the IDE regulations, that device is exempted from, among other things, misbranding, registration, listing, 510(k), performance standards, PMA, certain recordkeeping and reporting requirements, and GMPs. FDCA § 520(g), 21 U.S.C. § 360j(g); see also 21 C.F.R. part 812.

63. Among other things, the IDE regulations dictate various responsibilities for IDE sponsors and

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[38] Ibid.

investigators,[39] including obtaining patient-subject informed consent, record keeping, reporting requirements, and in addition, prohibits promotion and sale of the investigational device. (21 C.F.R. part 812.) The failure or refusal to comply with any IDE requirement, or to furnish any information required by the IDE regulations, is a prohibited act. FDCA § 301(q)(1), 21 U.S.C. § 331(q)(1). In addition, if a device is under an IDE, and the IDE sponsor or investigator fails to comply with a requirement of the IDE regulations, the device is considered adulterated. (FDCA § 501(i), 21 U.S.C. § 351(i)).

## Modifications of Already Cleared or Approved Devices [40]

64. For "510(k)ed" devices, a new 510(k) is required if the device is "about to be significantly changed or modified in design, components, method of manufacture, or intended use." 21 C.F.R. § 807.81(a)(3). The regulations specify the following as significant changes or modifications that require a 510(k): (1) a change or modification of the device that could significantly affect the safety or effectiveness of the device; or (2) *a major change or modification in the intended use of the device* [Emphasis added].

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[39] Note that a sponsor and investigator can be an individual, even the same individual.

[40] loc. cit. United States Department of Justice *Civil Resource Manual*.

65. For "PMAed" devices, the manufacturer is required to submit a supplement to its PMA before making a change "affecting the safety or effectiveness" of the device. 21 C.F.R. § 814.39(a).

66. The consequences of a failure to submit a necessary 510(k) or a necessary PMA supplement for a change to a device are the same as those for failing to make any necessary 510(k) or PMA submission.

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**Adulterated Devices**

67. A medical device is "adulterated" under 21 USC 351(f)(1)(B) if it is a Class III device and does not have an approved application for premarket approval in effect pursuant to 21 USC § 360e or an approved application for an FDA Investigational Device Exemption (IDE) pursuant to 21 USC § 360j(g).

68. UCLA Doctors' *New Device* is a Class III device by operation of law, which according to Plaintiff's communications with Defendant Drs. Swerdlow and Shivkumar, *infra*, had neither an approved application for premarket approval nor an approved application for an investigative device exemption (IDE) for the purpose of evaluating it as an "atrio-esophageal fistula condition diagnosis and prevention device." Therefore, use of the *New Device* in the experimental form of the ablation procedure to which NADINE was subjected was "adulterated," in violation of 21 USC 351(f)(1)(B), and could not be legally utilized without prior FDA

clearance.

**FDA IDE Approval Required for Medical Device Research**

69. *Clinical evaluations of investigational devices in any form or context, unless exempt, must at least have an approved FDA Investigational Device Exemption (IDE) before a device-related study on human subject is initiated.* According to FDA interpretation of investigational device regulations published in the FDA Center for Devices and Radiological Health on-line publication *Device Advice*,[41] "Investigational use also includes clinical evaluation of certain modifications *or new intended uses of legally marketed devices.* [Emphasis added.] All clinical evaluations of investigational devices, unless exempt, must have an approved IDE before the study is initiated"

70. *Thus, Defendants are subject to FDA Investigational Device Exemption Regulation whether or not they ever intended that the New Device be marketed.*

71. The only exception to this rule, discussed next, would be if UCLA Doctors were employing the *New Device* "off-label," in the practice of medicine. But, it was Drs. Swerdlow

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and Shivkumar themselves who explained to Plaintiff

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[41] http://www.fda.gov/cdrh/devadvice/ide/index.shtml.

that their use of the *New Device* was not "in the practice of medicine," but in the interest of medical research.

## UCLA Doctors Were Engaged in an Investigation of a Medical Device

72. As will be explained, *infra*,[42] Defendant Drs. Swerdlow and Shivkumar informed Plaintiff, that they knew nothing at all about the operational and performance characteristics of the Vital Signs Probe. They simply inserted it into patients' esophagus during catheter ablation procedures to "see if it would work" as an "atrio-esophageal fistula condition diagnosis and prevention device."

73. By their own admission, UCLA Doctors were engaged in an investigational study whose purpose it was to show that the Vital Signs Probe could be utilized to detect a particular kind of temperature rise in the esophagus which they *theorized* was of a character sufficient to cause the kind of thermal damage which they *speculated* leads to atrio-esophageal fistula formation.

74. Thus, an investigational enterprise whose purpose it is to demonstrate, in whole or in part, the use of a medical device for a new and novel purpose, whether expressly stated or implied, is an

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[42] See *The Experimental Form of the Ablation Procedure Revealed*, at page 40, *infra*.

investigational study subject to FDA regulation.[43]

75. According to the UCLA *Human Research Investigator's Manual*, at page 9-7,

> FDA permits the "off-label" use of an approved product (for a purpose or at a dosage different from approved uses) in the course of professional practice -- i.e., for care of individual patients. When it occurs with the intention of contributing to generalizable knowledge, however, or the physician contemplates reporting the results -- even as a collection or series of case studies -- the activity is viewed as research and thus is subject to prior HSPC review and approval.

76. Thus, when the intent is the "practice of medicine," directed at an individual patient, and a medical device is used in a manner that is not approved in the labeling, the FDA does not require the submission of an Investigational New Drug Application, Investigational Device Exemption, or review by an Institutional Review Board. But, according to the FDA, it is the physician's responsibility to *base off label use on firm scientific rationale and on sound*

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[43] See footnote 72 at page 50 for FDA requirements for "off-label" use of drugs and devices.

*medical evidence* and to document the product's use and effects. However, if the physician uses or plans to use data collected from off-label use of an approved drug or device as a demonstration or to prove or disprove an hypothesis, this is "research" and the physician must then follow the regulations and guidelines as put forth in the Code of Federal Regulations including obtaining FDA and IRB approval.

77. The experimental form of the ablation procedure incorporated an experimental demonstration of the Vital Signs Probe's ability to function as an "atrio-esophageal fistula condition diagnosis and prevention device." No such device is now marketed anywhere in the world. And, the *New Device* bore no resemblance whatsoever to the FDA approved Vital Signs Probe from which it was derived. Moreover, Drs. Swerdlow and Shivkumar knew *nothing at all* about its performance characteristics.[44] Thus, UCLA Doctors could not meet the FDA requirement that off-label use be based on firm scientific rationale and on sound medical evidence. Under these circumstances, the *New Deice* is a Class III device by operation of law (21 USC 360c(f)(1)), its application did not meet the requirements for off-label use, and thus could not be used on human subjects without prior FDA clearance.

78. And, the minimum FDA clearance which must be sought by at least one of the UCLA Doctors under these circumstances is an FDA Investigative

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[44] See *The Experimental Form of the Ablation Procedure Revealed*, at page 50, *infra*.

Device Exemption (IDE). This regulation required that UCLA Doctors obtain UCLA IRB approval (21 CFR 56), the informed consent of patient-subjects (21 CFR 50), and an FDA Investigational Device Exemption (IDE) that (1) was either expressly approved by the FDA under 21 CFR 812.20 or (2) automatically met criteria for an Investigational Device Exemption under 21 CFR 812.2. *But, evidently, UCLA Doctors fulfilled none of these requirements.*[45]

**The *New Device* Could Not Meet Requirements for an Automatic IDE Approval**

79. The *New Device* cannot meet the requirements of 21 CFR 812 for an FDA for an automatic Investigational Device Exemption because (1) it appears to be a Significant Risk

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device under 21 CFR 812.3(m) and (2) it cannot meet the conditions itemized in 21 CFR 812(c).

NADINE was Subjected to a Significant Risk Study

80. NADINE was subjected to a "Significant Risk" device study as defined in 21 CFR 812.3(m). The experimental form of the ablation procedure subjected NADINE to serious injury or death if the *New Device*

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[45] Ibid.

did not perform as envisioned by UCLA Doctors. And, it appears that the *New Device* did NOT perform as envisioned and this either resulted in or materially contributed to NADINE's untimely death.

81. According to FDA Information Sheets October 1, 1995, which replaces Bluebook Memorandum IDE Memorandum D86-1 (July 25, 1986) with the same title:

> The Investigational Device Exemption (IDE) regulations (21 CFR Part 812) describe two types of device studies, "significant risk" (SR) and "nonsignificant risk" (NSR). An SR device study is defined [21 CFR 812.3(m)] as a study of a device that presents a potential for serious risk to the health, safety, or welfare of a subject and (1) is an implant; or (2) is used in supporting or sustaining human life; or (3) is of substantial importance in diagnosing, curing, mitigating or treating disease, or otherwise prevents impairment of human health; or (4) otherwise presents a potential for serious risk to the health, safety, or welfare of a subject. An NSR device investigation is one that does not meet the definition for a significant risk study. NSR device studies, however, should not be confused with the concept of "minimal risk," a term utilized in the

> Institutional Review Board (IRB) regulations (21 CFR Part 56) to identify certain studies that may be approved through an "expedited review" procedure. *For both SR and NSR device studies, IRB approval prior to conducting clinical trials and continuing review by the IRB are required. In addition, informed consent must be obtained for either type of study (21 CFR Part 50).* [Emphasis added.]

82. Thus, an automatic IDE approval requires that the New Device be "other than a Significant Risk device" (21 CFR 812.2(b)(1). Plaintiff asserts that this requirement cannot be met because application of the *New Device* to guide the ablation procedure so as to purportedly avoid the fatal atrio-esophageal fistula complication places it in the category of a significant risk devices as defined in 21 CFR 812.3(m)(3) and 21 CFR 812.3(m)(4), *supra*.

**The *New Device* is not in the Class of FDA Exempted Investigations**

83. The *New Device* cannot be exempted as provided for in 21 CFR 812(c), "Exempted investigations," because it cannot meet the requirement that its use be noninvasive under 21 CFR 812(c)(3)(i).

84. "Noninvasive" as it relates to this case, is defined in 21 CFR 812.3(k)(2), and

when applied to a diagnostic device or procedure, such as the *New Device* means a device that does not by design or intention: "enter the ear beyond the external auditory canal, the nose beyond the nares, the mouth beyond the pharynx, ..." The *New Device* was placed well beyond NADINE's pharynx down to the level of her heart.

**Defendants were at Minimum, Required to Make Application for an FDA IDE**

85. Because the New Device could not meet the requirements for automatic IDE approval, under 21 CFR 812.3(m) and would not under 21 CFR 812(c), UCLA Defendants were required to submit a formal application according to the procedure specified at 21 CFR 812.20, et. seq., in order to receive express IDE approval from the FDA. According to Plaintiff's communications with Drs. Swerdlow and Shivkumar,[46] they did not.

**Use of the *New Device* Required NADINE'S Informed Consent**

86. All device studies require a patient's informed consent. 21 CFR 50.20 requires that before a

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[46] See *The Experimental Form of the Ablation Procedure Revealed*, at page 40, *infra*.

person becomes a subject in a clinical investigation, his or her "legally effective informed consent" must be obtained under circumstances "that provide . . . sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence." The federal regulations require the subject to be informed the study involves research, and to be told which procedures are experimental. (21 C.F.R. 50.25(a)(1) ). They also require the subject to be given a copy of the written consent form. (21 CFR 50.27(a).) None of these requirements were met. NADINE was never informed that she would be subjected to an experimental form of the ablation procedure utilizing an equally experimental *New Device*.

**NADINE Did NOT Consent to UCLA Doctors' Violation of the FDCA**

87. The FDCA is intended to protect the public from, *inter alia*, medical devices which do not conform to FDCA performance and safety requirements. NADINE is a member of the public entitled to the protections of the FDCA. The experimental form of the ablation procedure, exploring the use of an equally experimental *New Device*, required at least FDA IDE approval under 21 CFR 812 which included NADINE's informed consent under 21 CFR 50, and

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UCLA IRB approval under 21 CFR 56, BEFORE UCLA

Doctors could legally subject NADINE to its use in the manner contemplated by the experimental form of the ablation procedure.

88. *Defendants could not and/or did not meet any of these legal obligations*. NADINE was neither approached for nor did she give her consent to the experimental form of the ablation procedure. Consequently NADINE was surreptitiously subjected to a medical research experiment that embraced the evaluation of a new medical device that failed to perform as envisioned. UCLA Defendants knew or should have known that they could not perform the experimental form of the ablation procedure on NADINE, or for that matter anyone, without first fulfilling their legal obligations under the FDCA as described, *supra*. Yet UCLA Doctors did so with full knowledge and/or reckless disregard for NADINE's legal rights and safety, and it was the violation of these duties in surreptitiously subjecting NADINE to the experimental form of the ablation procedure that caused or contributed to her untimely death.

## II
## California Health and Safety Code § 24170, et. seq.

89. UCLA's obligation toward the public, including NADINE under the California Health and Safety Code was interpreted by Defendant Regents of the University of California's Office of the General Counsel, in a legal opinion letter dated 20 December

1996,[47] which is incorporated as Appendix 13 of the UCLA *Investigator's Manual for the Protection of Human Subjects*. It is directed at and applies to all UC campuses and research activities. It states in pertinent part:

> Health & Safety Code Section 24170, et seq. (the "Protection of Human Subject's in Medical Experimentation Act", hereinafter referred to as the "Act") sets forth the bill of rights for any human subject participating in an experimental study in California. Section 24172, subdivision (j) requires that the subject "[b]e given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision." In addition, section 24175, subdivision (a) provides;
>
> > "Except as otherwise provided in this section, no person shall be subjected to any medical experiment unless the informed consent of such person is obtained."

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[47] See Exhibit A.

The phrase "medical experiment" is defined broadly in section 24174 to mean:

> "(a) The severance or penetration or damaging of tissues of a human subject or the use of a drug or device as defined in Section 26009 or 26010, electromagnetic radiation, heat or cold, or a biological substance or organism, in or upon a human subject in the practice or research of medicine in a manner not reasonably related to maintaining or improving the health of such subject or otherwise directly benefitting such subject."
>
> "(b) The investigational use of a drug or device as provided in Sections 26678 and 26679."
>
> "(c) Withholding medical treatment from a human subject for any purpose other than maintenance or improvement of the health of

such subject."

> Based upon the foregoing, it does not appear that there are any applicable exceptions in California law to the requirement for *prior consent*. If the patient is unable to consent on his or her own behalf, the patient's legally authorized representative (a court appointed conservator or guardian, an attorney-in-fact - pursuant to a durable power of attorney, or parent) may consent on their behalf. *If there is no legally authorized representative and the patient cannot consent, the patient may not be a human subject in a medical experiment in California*. [Emphasis added.]

90. This statement of opinion by the Office of General Counsel for the Regents makes clear that California Health and Safety Code § 24170, et. seq. provides broad protections for the public including NADINE. It also makes clear that the experimental form of the ablation procedure utilizing the *New Device* could not be legally performed on NADINE without her informed consent under the Regents' own interpretation of Health and Safety Code § 24170, et. seq.[48]

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[48] It is noteworthy that Regents Office of General Counsel's interpretation of legal sanctions for which UC personnel could be liable, makes clear that there is no government-related immunity

## NADINE Did NOT Consent to UCLA Doctors' Violation of the Health and Safety Code

91. Plaintiff asserts that the experimental form of the ablation procedure could not fulfil the requirements of Health and Safety Code § 24174 (a) and (b). The experimental form of the ablation procedure was not conceived to benefit NADINE as an individual patient. Rather, NADINE was merely one patient-subject in a larger systematic study. At the time of her ablation procedure NADINE was apparently patient number 14 in the series of patients who were

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subjected to the experimental form of the ablation procedure, which results were later published.[49] Thus, the experimental form of the ablation procedure was an investigational medical experiment of the kind for which informed consent is required under California Health and Safety Code § 24170, et. seq.

92. These statutes were enacted to protect the public, including NADINE, from unwilling and/or unwitting participation in medical research. NADINE was neither approached for nor did she give her consent to the experimental form of the ablation procedure.

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for violation of these statutory safeguards.

[49] See *Publication of "Less Than Entirely True" Research Results*, at page ?, *infra*.

UCLA Defendants knew or should have known that they could not perform any form of medical research experiment on NADINE, or for that matter anyone, without the patient-subject's fully informed consent as provided for under, *inter alia*, Health & Safety Code § 24173 *(Informed Consent)* and § 24172 (*Experimental Subject's Bill of Rights*). Yet UCLA Doctors did none of these things with full knowledge and/or reckless disregard for NADINE's legal rights and safety, and it was the violation of those duties in surreptitiously subjecting NADINE to the experimental form of the ablation procedure that caused or contributed to her untimely death.

## III
## Policies Enacted by the Regents of the University of California for the Protection of Human Subjects in Medical Experimentation on All Campuses *(UC Contract & Grant Manual)*

93. The Regents of the University of California have established policies and procedures regarding the safety of human subjects in experimentation for all University of California campuses, including UCLA. These policies and procedures are found in Section 18 of the *UC Contract & Grant Manual* (effective 1/1/96, and as amended).

94. It should be noted that the policies stated *infra* have the force of law by operation of the Regent's position as an independent agency of government.

95. The specific policies applicable to this case

and that define the protections owed to the public and NADINE by UCLA Defendants include:

Section 18-210 Basic policy

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> The University of California is committed to the ethical principles for the protection of human subjects in research set forth in the Belmont Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The University recognizes and accepts responsibility, which it shares with its investigators and other researchers, for determining that research involving human subjects fulfills these ethical principles.
>
> The basic ethical principles outlined in the Belmont Report which guide the Institutional Review Board's deliberations and decision-making include respect for persons, beneficence, and justice. A summary of these principles follows:
>
> 18-210 (a). Respect for persons dictates that researchers must obtain informed consent from all human subjects invited to participate in research. In order to respect

subject autonomy, the consent process includes giving subjects full and comprehensible information about the research and providing a clear assurance of the subjects' voluntary participation.

18-210 (b). Beneficence is the essence of concern for the well-being of subjects, and requires that the risk of harm to subjects is the least possible, and that the sum of benefits to the subject and the importance of the knowledge to be gained so outweigh the remaining harm as to waive a decision to allow this risk.

Section 18-220 Applicability of Governmental Regulations and Policies to All Research

It is University policy that the regulations of the Department of Health and Human Services (HHS), set forth in 45 CFR Part 46, are applicable to *all research involving human subjects, as defined by these regulations, for which the University is responsible, regardless of the source of funding or whether the research is funded.* [Emphasis added] In the case of conflict between regulations of the funding or regulatory agency and HHS, the more restrictive regulations shall prevail. The

University is also obligated by law to adhere to the regulations of the Food and Drug Administration (21 CFR Parts 50 and 56) governing projects involving investigational new drugs [within the meaning of 21 U.S.C. sections 355(i) or 357(d)], or investigational new devices [within the meaning of 21 U.S.C. section 360(g)].

Section 18-230 Responsibility for Compliance

The Chancellors, the Senior Vice President--Academic Affairs, the Vice President--Agriculture and Natural Resources, and the Directors of the Department of Energy Laboratories are responsible for compliance with the University's policies applicable to human subjects. They are authorized to take appropriate action to implement the human subjects regulations of all funding or regulatory entities covering activities under their jurisdiction. In developing implementing procedures for research, the Chancellors, Vice Presidents and Directors shall establish a process for determining whether an activity constitutes research under the regulations and whether the research activity is exempt from formal

review. As a minimum, such a process should provide for some form of consultation with investigators.

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Section 18-250 Human Subjects Institutional Assurance Requirements

It is University policy that each campus and Laboratory comply with current Department of Health and Human Services policy requirements to provide written assurances acceptable to the Office for Protection from Research Risks, National Institutes of Health, Department of Health and Human Services. The specific instructions for preparation of such assurances are set forth in 45 CFR Part 46.103. The assurance must include statements of the responsible campus or Laboratory official (generally, the Chancellor or Laboratory Director) which certify (a) the institution's discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution, regardless of source of funding, (b) the designation of one or more Institutional Review Boards (IRBs) established in accordance with HHS

requirements, including a list of the IRB members identified by name and qualifications, and (c) the written procedures which the IRBs will follow. Detailed requirements of these elements and other assurance requirements are presented in 18-251 through 18-254.

Section 18-251 Statement of Principles

The assurance must contain a statement of principles governing the campus' or Laboratory's discharge of its responsibilities for protecting the rights and welfare of human subjects in research and may include an appropriate existing code, declaration, or statement of ethical principles, or a statement formulated by the campus itself. The University has adopted and incorporated the Belmont Report (see 18-210 and 18-F11) as its basic statement of ethical principles in its human subjects policy. Refer to 18-X01, Declaration of Helsinki and 18-X02, Nuremberg Code, as other examples of universally accepted statements of ethical principles concerning human subjects in research.

Doctrine of Informed Consent

A. Definition

Informed consent means the knowing consent of an individual (or of a legally authorized representative when a vulnerable or dependent person is to be involved) to his or her participation in a research activity without coercion or undue influence. Consent information, oral or written, must be expressed with words and in a language which are understandable to the subject or the representative. The text of the consent information must not involve any exculpatory language through which the subject is made to waive, or to appear to waive, any legal rights, including release of the University or its agents from liability for negligence. All subjects or their authorized representatives must receive a copy of any consent document which has been completed by them.

B. Summary of Basic Elements of Informed Consent

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and

identification of any procedures which are experimental;

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(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether any compensation or any medical treatments are available if injury occurs and, if so, what they consist of or where further information may be obtained;

(7) An explanation of whom to contact for answers to pertinent questions about the

research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject (see University policy for Medical Treatment of Human Subjects for Injuries Resulting from Participation in Research at 18-300); and

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Additional elements of Informed Consent to be used when appropriate are summarized in section 46.116 (b), 45 CFR, Part 46, Subpart A and section 50.25(b), 21 CFR, Part 50.

Section 18-F11 Belmont Report, "Ethical Principles and Guidelines for the Protection of Human Subjects of Research, Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research"

PURPOSE

The Belmont Report summarizes the basic ethical principles identified by the National Commission in the course of its deliberations as mandated by the National Research Act of July 12, 1974 (P.L. 93-348).

It is a statement of basic ethical principles and guidelines that should assist in resolving the ethical problems that surround the conduct of research with human subjects.

APPLICABILITY

The University of California has determined that the findings of the Belmont Report will apply to all human subject activities regardless of funding source for which the University is responsible.

SUMMARY OF PROVISIONS

**[Second Amended Complaint: Page 28; 1.CT.101]**

The summary of the provisions appears in 18-210.

UNIVERSITY POLICY IMPLEMENTATION AND PRIMARY UNIVERSITY RESPONSIBILITY

By Presidential policy memo dated September 2, 1981 the University of California adopted the ethical principles for the protection of human subjects set forth in the Belmont Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (see 18-210).

Primary responsibility for implementation is shared by Chancellors, Laboratory Directors, Institutional Review Boards, and Principal Investigators. The primary responsibility for judging or ascertaining if an extramural program or application falls under the provisions of the University's basic human subjects policy and has received the approval by the IRB rests with the Contracts and Grants Officers. For Office of the President activities and for policy review and compliance, the responsibility rests with the Senior Vice President--Academic Affairs or the Vice President--Agriculture and Natural Resources, as appropriate.

Section 18-F12 Federal Regulations on the Protection of Human Research Subjects

Identification

The Department of Health and Human Services (HHS) has issued regulations pursuant to the National Research Act (P.L. 93-348), which are codified in the Code of Federal Regulations under 45 CFR, Part 46.

There are four Subparts to Part 46 of the Code of Federal Regulations:

Subpart A - Basic HHS Policy for Protections of Human Research Subjects

Subpart B - Additional Protections Pertaining to Research, Development, and Related Activities Involving Fetuses, Pregnant Women, and Human In Vitro Fertilizations

Subpart C - Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects

Subpart D - Additional Protections for Children Involved as Subjects in Research

The Food and Drug Administration has issued regulations pursuant to the Federal Food, Drug and Cosmetic Act, which are codified in the Code of Federal Regulations under 21 CFR, Parts 50 and

56.

Purpose

To protect the rights and welfare of human subjects involved in biomedical and behavioral research which is supported by the Department of Health and Human Services.

Applicability

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Federal regulations codified under 45 CFR, Part 46, are applicable to HHS grants and contracts supporting biomedical or behavioral research, development, and related activities which involve human subjects.

a. Relation to Other Federal Agencies: 45 CFR, Part 46 also applies to human subject research supported by funds from the DOD, Commerce, Energy, HUD, Justice, Agriculture, State, Transportation, Treasury, EPA, USF, VA, USIA, the Consumer Product Safety Commission, the Civil Service Commission, and NASA, which have all adopted 45 CFR, Part 46, in whole or in

part, by reference.

b. *Applicability of Governmental Regulations and Policies to All University Research: University policy in 18-220 extends the regulations set forth in 45 CFR, Part 46 to all University research involving human subjects, regardless of funding source.* [Emphais added].

Federal Regulations codified under 21 CFR, Parts 50 and 56 are applicable to clinical investigations regulated by the Food and Drug Administration.

Section 18-F13 Informed Consent

Identification

45 CFR, Part 46, Subpart A (Section 46.116); and 21 CFR, Part 50 (Sections 50.20 and 50.25).

Purpose

To establish standards and compliance mechanisms for legally effective informed consent to permit the prospective subject or the representative sufficient opportunity to consider whether or not to participate as a subject in research

without coercion or undue influence.

**Summary of the Rights Conferred on NADINE by the Regents**

96. Under these policies, as established by the Regents of the University of California for all persons, including NADINE, who are involved in medical research of any kind, at any University of California facility, both approval by an Institutional Review Board (18-210(b), 18-220, 18-250) and legally effective informed consent (18-210(a), 18-220, 180-251) are required BEFORE any person can be subjected to any form of experimental research. NADINE Did NOT Consent to UCLA Doctors' Unlawful Conduct Under Regents' Policies.

97. These policies, which have the force of law, and were enacted to protect the public, including NADINE, against unwilling and/or unwitting participation in medical research conducted at any University of California facility. NADINE was neither approached for nor did she give her consent to the experimental form of the ablation procedure. UCLA Doctors knew or

**[Second Amended Complaint: Page 30; 1.CT.103]**

should have known that they could not perform any form of medical research experiment on NADINE, or for that matter anyone, without first receiving IRB

(Institutional Review Board) review and approval, *as well as* obtaining NADINE's fully informed consent. Yet they did none of these things with full knowledge and/or reckless disregard for NADINE's legal rights and safety, and it was the violation of those duties in surreptitiously subjecting NADINE to the experimental form of the ablation procedure that caused or contributed to her untimely death.

## IV
## Policies Enacted by UCLA for the Protection of Human Subjects in Medical Experimentation
## ( *UCLA Investigator's Manual for the Protection of Human Subjects*)

98. The UCLA *Investigator's Manual for the Protection of Human Subjects* [50] is evidently UCLA's institutional implementation of the Regents policy identified in Section 18-230, "Responsibility for Compliance," as contained in the *Contract & Grant Manual*, *supra*.

99. Under these circumstances, these policies have the force of law as they are a specific implementation of policies which themselves have he force of law under the University of California's status as a separate branch of government.

100. In the UCLA *Investigator's Manual for the Protection of Human Subjects*, the obligations of researchers such as Drs. Swerdlow, Shivkumar and Cesario toward patient-subjects are enumerated.

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[50] Pertinent sections are attached as Exhibit-B.

101. In the introduction, on page 1-2, UCLA defines research broadly, to wit:

> Research is defined in 45 CFR 46 as, "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." Human subjects are defined by the regulations as "living individual(s) about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information." The Institutional Review Boards (IRBs) at UCLA commonly referred to as the HSPCs, are required by federal regulations to review all University affiliated human subject research, regardless of funding, to ensure the rights, welfare, and protection of all subjects.

102. Section 4, Informed Consent Requirements, describes the extensive informed consent policies established as an essential element of *any* research involving human subjects.

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103. At no time while NADINE was under the

care of Drs. Swerdlow, Shivkumar and Cesario or UCLA were these requirements met.

104. At page 7-1 of Section 7, Responsibilities of Principal Investigators, is found the requirement that:

> Investigators are required to obtain a prospective UCLA HSPC review and approval if any of the following criteria exist:
>
> 1. When research with human subjects is conducted by or under the direction of any employee, student or agent of UCLA in connection with his or her institutional responsibilities, or
>
> 2. *When the conduct or recruitment of the research involves institutional resources (property, facilities or funding, including extramural funds administered by UCLA)* [emphasis added], or
>
> 3. When the research involves the use of UCLA's non-public information to identify or contact human research subjects or prospective subjects.
>
> 4. Investigators who transfer research to UCLA from their previous institution are required to submit the project to the HSPCs for review and approval in order to

continue the study.

105. Because the conduct of the research performed by Drs. Swerdlow, Shivkumar and Cesario on NADINE and others patients was carried out at UCLA Medical Center, a UCLA "property, " as stipulated in italicized point (2) above, the experimental form of the ablation procedure required UCLA HSPC review and approval. But, according to Plaintiff's communications with Drs. Swerdlow and Shivkumar *infra*, no UCLA HSPC review and approval was sought or granted.

106. In Plaintiff's communications with Drs. Swerdlow and Shivkumar *infra*, although they went to great lengths to describe their methodology to Plaintiff, they never acknowledged their obligations under either the policies established by the Regents of the University of California or UCLA to obtain the approval of an IRB (Institutional Review Board), such as the UCLA HSPC or to obtain patients' such as NADINE's informed consent to the medical research they surreptitiously performed as part of the experimental form of the ablation procedure.

107. According to Plaintiff's understanding of Drs. Swerdlow and Shivkumar's explanations of their treatment of NADINE, they simply "did it"-- and killed NADINE by these actions.

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## Nadine Did Not Consent to UCLA Doctors' Unlawful Conduct under UCLA Policies

108. These policies, which have the force of law, were enacted to protect the public, including NADINE, against unwilling and/or unwitting participation in medical research conducted at any UCLA facility. NADINE was neither approached for nor did she give her consent to the experimental form of the ablation procedure. UCLA Doctors knew or should have known that they could not perform any form of medical research experiment on NADINE, or for that matter anyone, without first receiving UCLA HSPC review and approval, *as well as* obtaining NADINE's fully informed consent. Yet they did none of these things with full knowledge and/or reckless disregard for NADINE's legal rights and safety, and it was the violation of those duties in surreptitiously subjecting NADINE to the experimental form of the ablation procedure that caused or contributed to her untimely death.

## Facts of Nadine's Untimely Death

### Nadine's Medical Condition

109. Decedent, NADINE F. SECAREA, suffered from cardiac arrhythmia for which she received pharmacological treatment, follow up consultations and occasional hospitalizations.

110. Due to the continued suffering experienced by NADINE, it was suggested that she undergo cardiac

catheter ablation to correct this condition.

**NADINE Selects Her Surgical Team**

111. After much research and searching, NADINE and Plaintiff interviewed Dr. Charles Swerdlow and Dr. Kalyanam Shivkumar in their offices at Cedars Sinai Medical Center and UCLA Medical Center, respectively.

**The Interview With Dr. Swerdlow**

112. Dr. Swerdlow advised NADINE and Plaintiff that, *inter alia*, the cardiac catheter ablation procedure was reasonably safe and effective when performed by knowledgeable and experienced electrophysiologist's at an equally knowledgeable and experienced hospital-institution.

113. Dr. Swedlow confirmed for NADINE and Plaintiff something that they had

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already been told, *to wit*, that, all other things being equal, a patient's outcome from an ablation procedure is primarily dependent on the skill of the electrophysiologist performing it.

114. NADINE and Plaintiff inquired as to Dr. Swerdlow's specific experience performing cardiac catheter ablation procedures. Dr. Swerdlow replied that he had been performing ablation procedures since 1984,

and he estimated that he had performed 1200 to 1300 catheter ablations during that time.

115. NADINE and Plaintiff inquired as to whether Dr. Swerdlow kept himself informed of the latest developments in cardiac catheter ablation. Dr. Swerdlow not only assured NADINE and Plaintiff that he did but, demonstrated his knowledge of the latest developments in cardiac catheter ablation by retrieving and displaying a recent article from the on-line medical literature on his desk-top computer. NADINE and Plaintiff explained to Dr. Swerdlow that not only skill, but a knowledge of the latest developments in cardiac catheter ablation science and its impact on NADINE's situation was an essential condition to NADINE's consenting to a physician's performing this procedure on her.

116. NADINE and Plaintiff inquired about how many ablation-related fatalities Dr. Swerdlow had encountered since he had been performing ablation. Dr. Sawerdlow answered "none." NADINE and Plaintiff went on to inquire as to how many resulted in serious complications. Dr. Swerdlow answered "none," although he confided that one of his patients experienced a heart attack during or just after one procedure, but the patient eventually recovered.

117. NADINE and Plaintiff inquired as to how Dr. Swerdlow could achieve such consistent results. Dr. Swerdlow replied that he was very selective about the patients he accepted for cardiac catheter ablations and that NADINE would be required to undergo an evaluation of her suitability for this treatment before he

would perform the ablation procedure on her.

118. Dr. Swerdlow went on to inform NADINE and Plaintiff that the cost for his extensive knowledge, skill and experience "wasn't cheap." Dr. Swerdlow stated that his charge for personally performing the ablation procedure would be $2000.

119. At some point Dr. Swerdlow inquired about Plaintiff's profession. Plaintiff

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explained that he was an engineer consulting on Aerospace projects.[51]

120. Dr. Swerdlow informed NADINE and Plaintiff that an ablation procedure was performed by a surgical "team of two" electrophysiologists. At the request of NADINE and Plaintiff, Dr. Swerdlow provided recommendations as to a second "ablation team member." One of these recommendations was Dr. Kalyanam Shivkumar. Dr. Swedlow explained that he and Dr. Shivkumar worked well together and often performed ablation procedures "as a team."

**NADINE Communicates Her Ablation Team Choice to Dr. Swerdlow**

121. After the interview with Dr. Swerdlow,

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[51] Plaintiff's educational background is Aerospace Engineering (BSAE), University of Pittsburgh. Plaintiff is engaged as an engineering consultant, currently involved in system simulation and modeling.

NADINE and Plaintiff agreed that, all other things being equal, it was important that her ablation surgical team not only be experienced as individuals, but also have some experience "working as a team." That such an opportunity would present itself to NADINE and Plaintiff was unexpected and it was the desire of NADINE and Plaintiff that this opportunity should not be lost.

122. In an e-mail dated 1 December 2003, NADINE wrote to Dr. Swerdlow:

> "My husband and I have talked it over and have decided that I should definitely go ahead with a catheter ablation. If possible, we'd prefer it to be done by you and Dr. Shivkumar from UCLA."

123. In fact two identical e-mails were sent to Dr. Swerdlow. The first was sent to "swerdlow@mail.ucla.edu." This was returned to NADINE and Plaintiff for want of the correct e-mail address for Dr. Swerdlow. On arriving home that evening, Plaintiff recognized the error and re-transmitted NADINE's message to the correct address "swerdlow@ucla.edu."

124. NADINE followed this e-mail with a telephone call to Dr. Swerdlow in order to discuss certain questions in the e-mail which required an extended discussion.

**The Interview With Dr. Shivkumar**

125. After communicating her ablation team choice to Dr. Swerdlow, NADINE and Plaintiff traveled to UCLA Medical center to interview Dr. Shivkumar, who had already discussed NADINE's condition with Dr. Swerdlow.

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126. Like Dr. Swerdlow, Dr. Shivkumar advised NADINE and Plaintiff, *inter alia*, the cardiac catheter ablation procedure was reasonably safe and effective when performed by knowledgeable and experienced electrophysiologists.

127. Like Dr.Swerdlow, Dr. Shivkumar advised NADINE and Plaintiff that, all other things being equal, a patient's outcome from an ablation procedure is primarily dependent on the skill of the electrophysiologists performing it.

128. NADINE and Plaintiff inquired as to Dr. Shivkumar's specific experience performing cardiac catheter ablation procedures. Dr. Shivkumar replied that he had been performing ablation procedures for about 5 years and he estimated that he had performed around 150-200 such procedures per year during that time.

129. NADINE and Plaintiff inquired about how many ablation-related fatalities Dr. Shivkumar had encountered since he had been performing ablation procedures. Dr. Shivkumar answered "none." NADINE

and Plaintiff went on to inquire how many resulted in serious complications. Dr. Shivkumar answered "none," but like Dr. Swerdlow, Dr. Shivkumar was very selective about the patients he accepted for the cardiac ablation procedure.

**Drs. Swerdlow and Shivkumar Agree to Perform NADINE's Ablation**

130. After interviewing Drs. Swerdlow and Shivkumar, NADINE informed them that she would agree to their personally performing the cardiac catheter ablation procedure on her, "as a team," as she had earlier stated in her 1 December 2003 e-mail to Dr. Swerdlow. Drs. Swerdlow and Shivkumar agreed to perform the ablation procedure on NADINE, subject to testing which would confirm her suitability for this procedure.

131. UCLA Medical Center was chosen as the place where NADINE'S ablation procedure would be performed because both Drs. Swerdlow and Shivkumar, who were professors of medicine at UCLA, had hospital privileges there.

132. Dr. Shivkumar handled NADINE's pre-procedure testing and evaluation.

133. During the months leading up to the cardiac ablation procedure, NADINE and Plaintiff made it clear to Drs. Swerdlow and Shivkumar that the ablation procedure was to be personally performed by them, as her surgical team, and no one else. NADINE was provided

literature from Drs. Swerdlow and/or Shivkumar and UCLA regarding the ablation procedure and both NADINE and Plaintiff relied on the representations made by Drs. Swerdlow and Shivkumar and UCLA regarding the ablation procedure contemplated for NADINE.

**Dr. Shivkumar's "Good Hands" Promise**

134. But, even after all the study and care that NADINE and Plaintiff had put into this decision, NADINE still expressed reservations about the ablation procedure and its complications. At some point, Dr. Shivkumar said to NADINE "stop worrying so much, you're in good hands." But, as Plaintiff was to learn to his eternal sorrow, anguish and regret, NADINE wasn't "in good hands." She would soon be in the worst possible predicament imaginable -- one that would take her life.

135. NADINE and Plaintiff exchanged telephone communications and e-mails with Dr. Shivkumar and his staff up to the time her ablation procedure was to be performed. In one telephone call, Plaintiff had discussed with one of Dr. Shivkumar's nurse-assistants whether Dr. Shivkumar, who was returning from a trip to India, only days before NADINE's scheduled ablation procedure, would be in a condition to perform it. Dr. Shivkumar's nurse-assistant assured Plaintiff that he would be. Plaintiff even

confirmed with Dr. Shivkumar, on the evening of 10 August 2004, that he would be capable of performing NADINE's ablation procedure the next day. He said that he was.

136. At no time did Dr Shivkumar or Dr. Swerdlow so much as even hint to Plaintiff or NADINE that they intended to involve NADINE in a speculative experimental procedure using a technique that both doctors admitted to Plaintiff was not based on any published or even unpublished scientific methodology.

**Ablation Procedure**
**Candidacy Testing at UCLA**

137. On or about July 29, 2004, NADINE underwent testing at UCLA to determine whether or not she was a good candidate for cardiac catheter ablation. She was determined to be an almost ideal candidate for a safe and successful ablation procedure per Dr. Shivkumar.

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**The Pre-Surgical Consultation with**
**Dr. Shivkumar at UCLA**

138. On the evening of August 10, 2004, a pre-surgical consultation was had with Plaintiff, NADINE and Dr. Shivkumar. Risk and benefits were discussed with Dr. Shivkumar. However, neither during this pre-surgical consultation nor at any

time prior to surgery or after, was mention of a fatal complication known as an atrio-esophageal fistula ever discussed and/or mentioned to the NADINE and Plaintiff, nor was such a complication ever discussed and/or mentioned in any of the literature provided to NADINE and Plaintiff, despite the fact that this complication was known to, or should have been known to, Drs. Swerdlow and Shivkumar and UCLA. It was UCLA who authored the "Informed Consent Information" which was in large part relied upon by NADINE and Plaintiff to decide whether or not to proceed with the ablation procedure. None of the literature supplied to NADINE mentioned the atrio-esophageal fistula complication notwithstanding that this almost always fatal condition had appeared in the scientific and medical literature for years prior to the date of NADINE's ablation procedure.

139. In addition, Dr. Shivkumar, in accordance with his agreement with NADINE that he and Dr. Swerdlow personally perform the ablation procedure, "as a team," indicated this fact on the "Consent to Operation and Other Procedures," that Plaintiff witnessed NADINE and Dr. Shivkumar sign. Moreover, in our long discussion with Dr. Shivkumar the evening of 10 August 2004, Dr. Shivkumar assured NADINE, at her request, when he and she signed the Consent to Operation and Other Procedures document, that he and Dr. Swerdlow would be performing the ablation procedure, and identified the other "physicians" and "associates" mentioned in that consent as the anesthesiologist, nurses, and other "support" personnel.

140. Another document that NADINE signed was entitled "Terms and Conditions of Service Confidentiality of Information" (or words to that effect). This "Terms and Conditions Agreement" also became a point of some discussion with Dr. Shivkumar. The document contained a "Teaching Hospital" (or words to that effect) clause which said, in essence, that medical personnel-in-training might be "observers" of the undersigned patient's care. When Plaintiff read this clause in the Terms and Conditions Agreement that NADINE signed, his

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comment was: "its nice to know that they [medical personnel-in-training] can look, but they can't touch."

141. This wasn't merely an off-handed comment on the part of Plaintiff, because had Dr. Shivkumar, or anyone else, even suggested to NADINE and Plaintiff that one of the documents that NADINE had signed relieved Drs. Swerdlow and Shivkumar from fulfilling their obligation to personally perform the ablation procedure on NADINE, "as a team," we would have left UCLA Medical Center, straight away. There would have been no ablation procedure performed on Nadine at UCLA Medical Center on 11 August 2004, NADINE would be alive, and Plaintiff would not be writing this account.

## The Experimental Ablation Procedure is Performed at UCLA

142. On or about August 11, 2004, NADINE underwent a cardiac catheter ablation procedure that lasted approximately 7½ hours. However, unbeknownst to NADINE and Plaintiff at the time, and without NADINE'S knowledge or consent, defendant, Dr. Cesario, an inexperienced understudy being trained as an electrophysiologist by Drs. Swerlow and Shivkumar, performed all, or a material portion, of the ablation procedure.

143. Although Dr. Shivkumar and Dr. Swerdlow had assured NADINE that they would personally perform the ablation procedure, as her surgical team, Dr. Shivkumar was only present in the electrophysiology laboratory at the beginning of the procedure just prior to NADINE's going under general anesthesia, then he left and did not return until the procedure was almost complete.

144. After the procedure was completed, Dr. Cesario, and later Dr. Shivkumar, informed NADINE and Plaintiff that the procedure was a complete success.

145. However, at no time prior to NADINE's demise was it ever disclosed to NADINE or Plaintiff that the surgical team to which NADINE had expressly consented to personally perform this procedure had not done so, but instead, (1) NADINE's ablation procedure was transformed into "on-the-job training" for the benefit of Dr. Cesario, and (2) NADINE had been subjected to an experimental form of the ablation

procedure which transformed her from "patient" into "laboratory animal," all to her detriment.

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**NADINE's Discharge from UCLA**

146. NADINE was kept overnight and discharged from UCLA on or about August 12, 2004, having been prescribed anticoagulants upon discharge. Dr. Swerdlow was to handle NADINE's post-surgical care and treatment.

147. But, at no time was NADINE provided with a post-surgical examination to evaluate the success or failure of the experimental ablation procedure to which she had just been surreptitiously subjected and at no time was she ever informed that the ablation procedure to which she agreed never took place. Instead her body was used as a "laboratory animal" to satisfy the medical research and publishing ambitions of the UCLA Doctors.

**NADINE Suffers a TIA**
(Transient Ischemic Attack).

148. On or about September 6, 2004, NADINE experienced visual disturbances along with tingling and numbness in her hands and arms. NADINE and Plaintiff telephoned, and later spoke with, Dr. Swerdlow regarding the symptoms as stated, only to be advised to "wait and see." No mention of the fatal atrio-

esophageal fistula as a complication to cardiac ablation was mentioned at this point in time or at any time before.

149. Shortly after consulting with Dr. Swerdlow about the complaints of experiencing the visual disturbances, NADINE collapsed and lost consciousness.

**NADINE is Rushed to the Irvine Regional Emergency Room**

150. NADINE was transported emergently by ambulance to the emergency room of Irvine Regional, where she was examined and treated by Dr. Swartzentruber and Dr. Schwartz. NADINE also presented with, among her other symptoms, hematemesis. Due to NADINE's severe symptoms, Dr. Schwartz admitted her to a telemetry unit in the early morning hours of September 7, 2004. Drs. Swartzentruber and Schwartz were informed of NADINE's previous cardiac catheter ablation and her current dependence on coumadin, as well as Drs. Swerdlow and Shivkumar as constituting her ablation surgical team. Drs. Swarzentruber and Schwartz did not, and could not, determine what was wrong with NADINE, nor did they attempt to contact either Dr. Swerdlow or Dr. Shivkumar. Instead, Plaintiff, after several attempts, made contact with Dr. Swerdlow and informed him of NADINE'S situation.

**[Second Amended Complaint: Page 40; 1.CT .113]**

## NADINE's Second Stroke Sends her to the ICU

151. At some point in the afternoon hours of September 7, 2004, Plaintiff observed NADINE fall unconscious, prompting a "code blue" response and eventual transfer to the intensive care unit (ICU). During this time and before, Plaintiff was attempting to make contact, and ultimately did make contact with Dr. Swerdlow.

152. On September 8, 2004, after an electroencephalogram was performed, Plaintiff was informed that NADINE had suffered a stroke that could have affected about 80-90% of her cognitive abilities and from which she was unlikely to awaken.

153. On or about September 8, 2004, and times thereafter, Dr. Swerdlow first discussed with Plaintiff the fatal atrio-esophageal fistula complication to the cardiac catheter ablation procedure and informed Plaintiff that he had discussed this complication with the doctors at Irvine Regional.

154. Drs. Swerdlow and Shivkumar subsequently revealed to Plaintiff not only the complication of atrio-esophageal fistula resulting from a cardiac catheter ablation procedure, but:

a) That their inexperienced understudy, Dr. Cesario, took an active role in the material and critical portions of the ablation procedure, as part of his training as an electrophysiologist, unbeknownst to, and unconsented to by, NADINE and Plaintiff, and despite Drs. Swerdlow's and Shivkumar's assurances that they would personally perform the ablation procedure; and

b) That NADINE had been subjected to an experimental form of the ablation procedure, which was in reality, a medical research experiment.

## The Experimental Form of the Ablation Procedure Revealed

155. During the time NADINE lay motionless in the Irvine Regional ICU, and in communications with Drs. Swerdlow and Shivkumar that extended through 28 October 2004, Plaintiff learned the details of what Drs. Swerdlow, Shivkumar and Cesario had done to her.

### Overview

156. Drs. Swerdlow and Shivkumar described to Plaintiff the particulars of the medical

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research to which they subjected NADINE. The facts that Drs. Swerdlow and Shivkumar revealed to Plaintiff, along with additional inquiry done by Plaintiff, showed that:

(1) NADINE was subjected to a medical experiment, whose end and aim was not to benefit NADINE as an individual, but simply to provide data for expanding and publishing generalized medical knowledge about the atrial-esophageal fistula complication. According to Dr. Swerdlow, NADINE was apparently patient number 14 in this experimental

series.[52]

(2) Drs. Swerdlow and Shivkumar concealed from NADINE their publication interest in the medical experiment they were performing on her.

(3) Drs. Swerdlow and Shivkumar did not seek NADINE's informed consent before involving her in their research on the experimental form of the ablation procedure, as required by California Health and Safety Code § 24170, et. seq.[53]

(4) The UCLA Doctors did not seek UCLA IRB (Institutional Review Board) approval prior to conducting this research.[54]

(5) The UCLA Doctors did not seek FDA certification or approval to evaluate the use of the Vital Signs Probe in a new and novel way that had no relation to the device's FDA approved intended use.[55]

(6) UCLA Doctors did not seek UCLA IRB approval and NADINE's informed consent to evaluate the use of the Vital Signs Probe in a new and novel way that had no relation to the device's FDA approved

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[52] E-mail communication dated 12 October 2004.

[53] See *III. California Health and Safety Code § 24170, et. seq.*, at page 22, *supra*.

[54] See *IV. Policies Enacted by the Regents of the University of California for the Protection of Human Subjects in Medical Experimentation on All Campuses*, at page 24, *supra*, and *V. Policies Enacted by UCLA for the Protection of Human Subjects in Medical Experimentation*, at page 30, *supra* and 45 CFR 46.

[55] See *I. Federal Food, Drug, and Cosmetic Act ("FDCA")*, at page 12, *supra*.

intended use and which involved a significant risk study.[56]

157. In sum, UCLA Doctors at NO time indicated to Plaintiff that they had ever sought

**[Second Amended Complaint: Page 42; 1.CT .115]**

the approvals required by law for conducting this medical research, and records received from UCLA by Plaintiff seemed to confirm that they hadn't.

## The Communications with Drs. Swerdlow and Shivkumar [57]

158. After NADINE had been taken to the Irvine Regional ICU, Dr. Swerdlow finally responded to the several telephone calls Plaintiff had place to him at his office – which was the only contact information Plaintiff had for him. Dr. Swerdlow listened to Plaintiff's description of events then informed Plaintiff that he needed to discus NADINE's condition with her Irvine Regional attending physicians.

159. The next day Dr. Swerdlow spoke with Plaintiff. He opined that NADINE might be suffering

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[56] See *NADINE was Subjected to a Significant Risk Study*, at page 20, *and* Use of the New Device Required NADINE'S Informed Consent, at page 21, *supra*.

[57] The accounts *infra* are not intended to a be a "time-line transcript" of Plaintiff's communications with Drs. Swerdlow and Shivkumar, but an account of what was learned from them about their treatment of NADINE.

from a complication known as an atrio-esophageal fistula. Dr. Swerdlow advised Plaintiff that he would work with the Irvine Regional doctors to investigate this possibility.

160. During that week, in discussing the atrio-esophageal fistula complication with Plaintiff, Dr. Swerdlow and later Dr. Shivkumar revealed that they had learned about this problem around April of 2004 [58] form a scientific article published by Pappone, et. al., in the journal *Circulation* [59] (hereinafter, the *Pappone Scientific Paper*).

161. Plaintiff asked Dr. Swerdlow if he could provide a copy of the article. Dr. Swerdlow informed Plaintiff that he had faxed this paper to NADINE's physicians at Irvine Regional. Plaintiff looked for the article and finally located it in NADINE's medical chart.

162. Plaintiff inquired as to why he and NADINE had not been informed of the existence of this complication before her procedure, but neither Dr.

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[58] Drs. Swerdlow and Shivkumar may have only learned of the atrio-esophagea fistula complication around April 2004, but Plaintiff discovered that it has appeared in the medical scientific literature since bout 2001 (See Gillinov A, Pettersson, Rice T. "Esophageal injury during radiofrequency ablation for atrial fibrillation," *J Thorac Cardiovasc Surg*. 2001; 122: 1239–1240).

[59] Pappone C, Oral H, Santinelli V, Vicedomini G, Lang CC, Manguso F, Torracca L, Benussi S, Alfieri O, Hong R, Lau W, Hirata K, Shikuma N, Hall B, Morady F., "Atrio-esophageal fistula as a complication of percutaneous transcatheter ablation of atrial fibrillation." *Circulation*. 2004;109: 2724–2726. (*Pappone Scientific Paper*)

Swerdlow or Dr. Shivkumar

**[Second Amended Complaint: Page 43; 1.CT .116]**

provided an answer to that inquiry. They merely side-stepped the issue by changing the topic of discussion. Plaintiff was particularly disconcerted by Dr. Shivkumar's lack of rationale for not disclosing these facts to NADINE and Plaintiff on the evening of 10 August 2004, since the major topic of discussion that evening was the complications associated with the ablation procedure, and Dr. Shivkumar knew (or should have known) that, the very next day, NADINE was to be "patient number 14" in an experimental series which involved medical research into the atrio-esophageal fistula complication.

163. Both Dr. Swerdlow and Dr. Shivkumar described the details of the experimental form of the ablation procedure to Plaintiff. Each provided insights that helped Plaintiff to understand the basic concepts, and misconceptions, of their research and to assemble the facts that, over many months of study on the part of Plaintiff, became the basis of this Complaint.

164. During his communications with both Drs. Swerdlow and Shivkumar, Plaintiff discussed the details of the experimental form of the ablation procedure which Plaintiff ultimately came to understand as being a based on "esophageal temperature measurement."

165. Plaintiff inquired of Dr. Swerdlow as to what had motivated him and Dr. Shivkumar to pursue the experimental form of the ablation procedure. Dr.

Swerdlow said that it was the *Pappone Scientific Paper*.

166. Plaintiff acquired a copy of the *Pappone Scientific Paper* to see for himself what Dr. Swerdlow could have meant. But, as Plaintiff studied the paper, he found only one reference to esophageal temperature measurement, to wit:

> [F]urther studies are required to monitor temperature changes in the esophagus during the creation of lesions. [60]

There was nothing more. Plaintiff, himself an applied scientist, came to understand that Drs. Swerdlow and Shivkumar had subjected NADINE, and other patients, to a research study whose true purpose was to do nothing more than to fill an information void by conducting the "studies" suggested by the *Pappone Scientific Paper* – and publishing the results. In other words, the true motivation for the experimental form of the ablation procedure was medical research.

**[Second Amended Complaint: Page 44; 1.CT .117]**

167. Plaintiff inquired of Drs. Swerdlow and Shivkumar as to what the esophageal temperature measurement, incorporated as part of the ablation procedure was intended to accomplish and how a measure of temperature was expected to achieve this result.

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[60] Ibid. at page 2726.

168. Drs. Shivkumar explained that the goal of a catheter ablation is the transmural destruction of a thin line of heart tissue which, when healed into scar tissue, acts as a conduction block to the electrical pathways which give rise to the kind of cardiac arrhythmia suffered by NADINE and other patients with the same or similar condition.

169. Plaintiff inquired into the meaning of the word "transmural." Dr. Shivkumar explained that this meant that the damage done to the heart tissue by the ablation procedure extends completely through the heart muscle and that the heat energy generated by the RF catheter can even damage adjacent organs – like the esophagus.

170. Plaintiff complained to Dr. Shivkumar that the possibility of damage to adjacent organs was a complication that he and Dr. Swerdlow should have discussed with NADINE and Plaintiff before the time of NADINE's procedure.[61] Moreover, neither of them had described the lesions (injury to tissue) they intended to create within NADINE's heart as "transmural."

171. Until this discussion with Dr. Shivkumar, which took place after NADINE's death, NADINE and Plaintiff were led to understand that the tissue damage

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[61] Plaintiff points out that there is a considerable difference between consenting to a procedure that creates tissue damage that is confined to a very localized region of tissue and consenting to a procedure that can cause tissue damage extending far beyond the region where it is created. To Plaintiff, it's the difference between a "scratch" and a "rupture."

caused by the ablation procedure was rather superficial and in any event limited only to the heart tissue directly under the ablation catheter.

172. Dr. Shivkumar explained that it was damage to the esophagus that was probably the most problematic and deadly. It was this difficulty that he and Dr. Swerdlow believed they could solve with the experimental form of the ablation procedure. Thus, as Plaintiff understood them, Drs. Swerdlow and Shivkumar had *theorized* that by looking for an abrupt temperature rise in the esophagus, as the measure of when to cut off power to the ablation catheter, they could

**[Second Amended Complaint: Page 45; 1.CT.118]**

achieve transmurality of the ablated tissue, but still avoid thermal damage to the esophagus.

173. In practice, according to the explanation given Plaintiff, the esophageal temperature measurement to which NADINE was surreptitiously subjected, purported to detect an abrupt temperature rise in the esophagus which resulted from heating which was generated by the continuous application of RF energy to the left atrium posterior wall, by a catheter positioned approximately opposite the temperature probe in the esophagus. When the specified temperature rise condition is detected, the power to the RF catheter is immediately terminated and, *theoretically*, thermal injury to the esophagus, such as the atrio-esophageal fistula that took NADINE's life, could be avoided.

Morecver, this description is essentially what Drs. Swerdlow, Shivkumar and Cesario published pursuant to their presentation at the *2005 American College of Cardiology Annual Scientific Session*.[62]

174. Plaintiff learned that, in NADINE's surgery, one of the points which constituted the ablation line across her left atrium posterior wall intersected the esophagus. While this point was being created (i.e. "burned"), the RF catheter was held in place and RF energy was allowed to "burn and burn and burn and burn" until the temperature probe in her esophagus registered a predetermined value, which, according to Drs. Swerdlow and Shivkumar, would be an *abrupt rise* of at least 0.5 $^{O}$ C.

175. But, as Plaintiff would eventually come to understand from Drs. Swerdlow and Shivkumar and the scientific and medical literature, it is a matter of speculation and conjecture as to whether the abrupt temperature rise condition that was employed in the experimental procedure to which NADINE was surreptitiously subjected is a true indicator of the conditions precedent to thermal injury to the esophagus.

176. The obvious consequence of such a supposition being incorrect is that even the most precise measurement of esophageal temperature will fail to protect a patient-subject from esophageal injury, including the atrio-esophageal fistula which took

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[62] Cesario, D., Shivkumar, K., Valderrabano, M., Wiener, I., Swerdlow, C., "Esophageal Temperature Monitoring During Left Atrial Catheter Ablation for Atrial Fibrillation," *J Am Coll Cardiol*. 2005 Feb 1;45(4):114A-115A (Abstract).

NADINE's life. In other

**[Second Amended Complaint: Page 46; 1.CT .119]**

words, by the time the temperature probe indicates an increase of any amount, the RF catheter may have already "burned a hole" through the heart's left atrium posterior wall and through the esophagus.[63]

177. Moreover, as Plaintiff understood Drs. Swerdlow and Shivkumar, it was not merely the temperature within the esophagus that they wished to monitor, it was the temperature of the esophagus wall ("esophageal lumen') directly across from the RF catheter positioned in the heart's left atrium. As an aerospace engineer, Plaintiff understood that such a precise measurement as this could require specialized

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[63] According to the clinical literature, although a fully formed fistula (hole or tunnel-like structure) can be burned through to the esophagus during the ablation procedure, there may also be just enough thermal damage to the esophagus so that a fistula doesn't form immediately, but over the span of weeks, as happened to NADINE. According to Plaintiff's reading, in all cases, the result is the same. If the "hole" (fistula) isn't plugged almost immediately, the patient dies. See for example the *Pappone Scientific Paper* at page 2726, which states in pertinent part:

> "Antimicrobial therapy alone appears not to improve the situation, and widespread gaseous or septic embolization will continue without prompt surgical intervention. Definitive treatment should be expedited once the diagnosis has been confirmed because rapid deterioration and death are likely."

sensors and instrumentation conceived for that purpose, depending on the character of the temperature profile being measured. This raised a number of technical questions for which Drs. Swerdlow and Shivkumar had no answer.

178. Drs. Swerdlow and Shivkumar could not explain to Plaintiff what role temperature, as a measured parameter, played in atrio-esophageal fistula formation or how the Vital Signs Probe could be relied upon to provide the desired data.

179. Plaintiff engineer, applying basic engineering analysis, observed that unless the role of temperature in atrio-esophageal fistula formation could be identified and a particular temperature value quantified, even the most accurate temperature measurement obtainable would be of questionable value or no use at all.

180. At Plaintiff's request, Dr. Swedlow provided NADINE's esophageal temperature readings to Plaintiff (such as they were), to wit:

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> Prior to Nadine's case, we had recorded esophageal temperature and correlated it with radiofrequency applications in 13 patients. Eleven of these patients had esophageal temperature rises $>0.5\,^{O}C$. In these patients, the maximum increase in temperature was $1.3 \pm 0.4$ C (range 0.8 - 1.6 ). In Nadine's case the maximum

temperature rise was 1.2 (from 37.1 to 38.3 ).[64]

181. NADINE's recorded esophageal temperature was in the range of those of 13 previous patients (whom Plaintiff has assumed suffered no ill effects). Given that NADINE was struck down by an atrio-esophageal fistula this experimental procedure was conceived to prevent, the experimental data could mean several things, one of which is that "temperature" alone is not a reliable measure of atrio-esophageal fistula susceptibility.

182. That is, the true parameters of atrio-esophageal fistula formation are unknown, therefore any measure which purports to provide an indicator of this condition is without scientific foundation. Moreover, past and current research on this subject supports this view.[65] [66]

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[64] E-mail communication dated 12 October 2004.

[65] Redfearn DP, Trim GM, Skanes AC, Petrellis B, Krahn AD, Yee R, Klein GJ., "Esophagealtemperature monitoring during radiofrequency ablation of atrial fibrillation." *J Cardiovasc Electrophysiol.* 2005 Jun; 16(6): 589-93. At page 592, the authors state that "The mechanism of injury to the esophagus during left-atrial ablation has not been defined . . ."

[66] Doll N, Borger MA, Fabricius A, Stephan S, Gummert J, Mohr FW, Hauss J, Kottkamp H, Hindricks G. Esophageal perforation during left atrial radiofrequency ablation: is the risk too high? *J Thorac Cardiovasc Surg.* 2003;125:836–842.(At page 840, the authors report that "[a]lthough the number of patients with esophageal perforation in the current study was small, it is

183. Even Dr. Swerdlow acknowledged to Plaintiff that the experimental form of the ablation procedure to which NADINE was subjected was purely theoretical and speculative. According to Dr. Swerdlow, at no time had he or Dr. Shivkumar scientifically vetted or tested their theory before practicing it on patients, like NADINE. In an e-mail to Plaintiff, Dr. Swerdlow stated that:

> There are no published (or to the best of my knowledge) unpublished esophageal-temperature data on which to base decisions about termination of radiofrequency energy delivery during left atrial ablation. [67]

184. Plaintiff cannot understand how UCLA Doctors could have surreptitiously

**[Second Amended Complaint: Page 48; 1.CT .121]**

subjected NADINE to a speculative course of medical research that Dr. Swerdlow admitted to Plaintiff was based on no known medical or scientific foundation that they knew of. They were simply "trying out" the experimental form of the ablation procedure "on unsuspecting patients "to see what happened." And,

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troubling that we were unable to identify any reliable predictors of this life-threatening injury.").

[67] E-mail communication dated 12 October 2004.

what happened was, UCLA Doctors killed NADINE.

185. In an earlier communication to Plaintiff, Dr. Swerdlow offered to help him in a literature search to aid his understanding of the biophysics of cardiac catheter ablation.[68] Plaintiff took Dr. Swerdlow up on his offer and sent him for the following request:

> I think I'm at a point where I could use your assistance with a literature search.
>
> I'd like to become familiar with the biophysics of RF ablation and fistula formation. If possible, I'd like to know how exposure of human tissue to RF energy, and the heat generated thereby, forms fistulas.
>
> The motivation for this inquiry comes, in part, from the paper you described to me while Nadine was in the ICU at Irvine Regional Hospital. I located the paper entitled, "Atrio-Esophageal Fistula as a Complication of Percutaneous Transcatheter Ablation of Atrial Fibrillation," in Nadine's chart and I acquired a copy for myself.
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> Although the paper describes some conditions under which atrio-esophageal

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[68] E-mail communication dated 6 October 2004.

> fistulas have occurred, it does not address the basic biophysics of fistula formation, nor does it shed any light on how measuring temperature in the esophagus might be useful in avoiding this condition. I concluded that I was missing some basic knowledge and that perhaps you could help me "fill in the blanks." [69]

186. Dr. Swerdlow never responded to this request and this e-mail was the last personal communication between Plaintiff and Drs. Swerdlow and Shivkumar.

187. The statements made by Drs. Swerdlow and Shivkumar to Plaintiff also indicated that they had not received IRB approval for this medical research as required by the policies established by the Regents (page 24, *supra*) and by UCLA (page 30, *supra*).

188. Given the foregoing, Plaintiff engineer determined that the lack of any reliable scientific basis for the experimental form of the ablation procedure that NADINE was surreptitiously subjected to was one of two fatal flaws in the experimental protocol that Drs.

**[Second Amended Complaint: Page 49; 1.CT .122]**

Swerdlow and Shivkumar had devised which this Plaintiff alleges either significantly contributed to or

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[69] E-mail communication dated 28 October 2004.

caused NADINE's untimely death.

189. The second fatal flaw in the experiments that defined Drs. Swerdlow's and Shivkumar's medical research was the issue of temperature measurement itself.

190. The Vital Signs Probe, the temperature measuring device actually used during NADINE's ablation procedure, was not designed or intended for this purpose. It is a matter of speculation and conjecture as to whether the "temperature" measured under these circumstances is a true indication of the temperature of the "dot-sized" area of the esophageal tissue actually affected by the heating action of the ablation catheter, and which could become an atrio-esophageal fistula.

191. When Plaintiff was informed by Drs Swerdlow and Shivkumar that an anesthesiologist's temperature probe had been used as the temperature measuring device for their experiment, Plaintiff inquired into intended use of an anesthesiologists temperature probe. Drs. Swerdlow and Shivkumar explained that the purpose of this device was to monitor core body temperature during surgery.

192. Plaintiff, then asked, both Dr. Swerdlow and Dr. Shivkumar in separate conversations, what led them to believe that they could use this device for a purpose for which it was neither designed of intended. That is, to measure the temperature generated at that portion of esophageal lumen across from an ablation catheter positioned in the heart's left atrium. This question, was met with silence by both physicians.

Neither Dr. Swerdlow nor Dr. Shivkumar could offer a rationale for this choice. And, Neither Dr. Swerdlow nor Dr. Shivkumar stated that they had obtained the FDA clearance required to evaluate the Vital Signs Probe as a "atrio-esophageal fistula condition diagnosis and prevention device" which is an *extreme* departure from the FDA approved application of this device to measure core body temperature.

193. When Plaintiff queried Dr. Swerdlow about the operating specifications of this device, Dr. Shivkumar provided Dr. Swerdlow the make and model number of the device used on NADINE (the VITAL-TEMP 1011-18Fr Series 400 Esophageal Stethoscope) and Dr.

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Swerdlow passed the information on to Plaintiff.[70]

194. When Plaintiff asked Dr. Swerdlow for operating specifications of the device used on NADINE, Dr Swerdlow replied that he didn't have any more information than the make and model of the device as was supplied by Dr. Shivkumar, but he believed that the Vital Signs Probe device was "a standard temperature probe used at UCLA." [71]

195. Thus, Plaintiff came to understand that the Vital Signs Probe was used in the experimental form of the ablation procedure for no other reason than it

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[70] E-mail communication dated 6 October 2004.

[71] E-mail communication dated 12 October 2004.

was "a standard temperature probe used at UCLA." To Plaintiff's scientific mind, *this was no reason at all.* Plaintiff concluded that Drs. Swerdlow and Shivkumar were "winging it" (to use a popular term among some engineers that denotes design decisions and actions which are not well thought out), [72] when they conceived

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[72] Plaintiff notes that the FDA would probably agree with this view. An FDA correspondence dated 17 February 1994, entitled "Update on the Regulatory Status of Pedicle Screws" states, *inter alia*, that whenever a physician uses an device in an "off-label" manner (i.e., using an approved device for an "unapproved" purpose):

> [i]n general, a physician who engages in off-label uses has the responsibility to be well informed about the device, and to base the decision to use it on sound medical evidence and a firm, scientific rationale.

Plaintiff asserts that Dr. Swerdlow's statement in his 12 October 2004 e-mail that there was no rationale at all for the use of the Vital Signs Probe in the experimental form of the ablation procedure, other than it existed, was reckless and indifferent to NADINE's rights and safety. The total lack of any understanding of this medical device's capabilities and limitations put the use of the Vital Signs Probe in a manner which did not conform to its FDA approved application soundly into the category of a medical device investigation or experiment -- which required, at minimum, an FDA Investigational Device Exemption (IDE).

It should also be noted that if one were to sanction the use of a device simply because it was available, such a policy would tend to justify a surgeon's performing an appendectomy with, say, a meat cleaver, simply because one was available. Plaintiff suggests that such a stance would reduce the practice of medicine to little more

the experimental form of the ablation procedure.

196. By their own admission, UCLA Doctors were engaged in an investigational study

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whose purpose it was to demonstrate that the Vital Signs Probe could be utilized to detect a particular kind of temperature rise in the esophagus whose character is sufficient to cause the kind of thermal damage which they *theorized* leads to atrio-esophageal fistula formation

197. In other words, Drs. Swerdlow and Shivkumar possessed no knowledge whatsoever as to whether the Vital Signs Probe could be used as envisioned. They were, in reality, experimenting to answer that question. Plaintiff has concluded that the answer to the question as to whether the Vital Signs Probe can be reliably employed as an "atrio-esophageal fistula condition diagnosis and prevention device" as envisioned by UCLA Doctors, was answered by NADINE's untimely death, and the answer is a resounding "NO!"

198. UCLA Doctors simply used the Vital Signs Probe and "hoped it would work." Plaintiff engineer observes that this approach is one method of evaluating a medical device. But, in Plaintiff engineer's opinion, it is one of the worst imaginable.

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than a set of arbitrary choices, any one of which is as good as any other.

199. The consequence to a patient-subject of this, and other unresolved issues of the experimental form of the ablation procedure, is that if the hypothesized results are not realized, then the RF energy being applied in the left atrium could, without any indication, "burn through" to the esophagus and result in thermal injury, including the atrio-esophageal fistula which took NADINE's life. According to Plaintiff engineer's analysis of the information available to him, this appears to be precisely what happened to NADINE.

200. Plaintiff further observes that it is this kind of conduct by Drs. Swerdlow. Shivkumar and Cesario that validates the critical role that the FDA and the FDCA play in protecting patients like NADINE form callous and reckless conduct carried out in the name of "medical research." Unfortunately, as numerous, broad and embracing as the statutes and policies designed to protect human subjects in experimentation may be, all of them completely failed NADINE and Plaintiff, because UCLA Defendants were able to and did hide their actions under a veil of secrecy, misrepresentation and deceit – until it was too late for NADINE.

201. Under these circumstances, there is every reason to conclude that NADINE's untimely death was, in large part, due to the use of a medical device that, in any event, required FDA approval under the FDCA to be incorporated in a research study which was in any manner

**[Second Amended Complaint: Page 52; 1.CT .125]**

evaluating its performance capability for a new and novel application.

202. Plaintiff believes that had UCLA Defendants followed these regulations as they were legally obligated to do, NADINE would be alive and well today, and Plaintiff would not be writing this account.

**Publication of "Less Than Entirely True" Research Results**

203. Drs. Swerdlow and Shivkumar never disclosed to NADINE and Plaintiff that they had a publication interest in the medical research they were performing on patients, including NADINE.

204. But, in February [73] and June [74] 2005, Plaintiff read accounts published in the *Journal of the American College of Cardiology* (JACC) which confirmed that NADINE had been subjected to a research study that neither she nor Plaintiff knew about or consented to.

205. Further investigation revealed that it was this experimental component that was likely responsible for NADINE's untimely death. As stated supra, Drs. Swerdlow and Shivkumar admitted to Plaintiff that (1)

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[73] Cesario, D., Shivkumar, K., Valderrabano, M., Wiener, I., Swerdlow, C., "Esophageal Temperature Monitoring During Left Atrial Catheter Ablation for Atrial Fibrillation," *J Am Coll Cardiol.* 2005 Feb 1;45(4):114A-115A (Abstract).

[74] Conti, J..B., "ACC 2005 Annual Session Highlights," *J Am Coll Cardiol* 2005; 45 Suppl B:32B.

the experimental form of the ablation procedure was not based on any reliable scientific or medical principle (page 90, *supra*) and (2) that the temperature probe used in this research was employed for no reason other than it existed. (page 94, *supra*).

206. As stated *supra*, Drs. Swerdlow and Shivkumar, et. al., reported the results of their experimental study at the 2005 American College of Cardiology (ACC) Annual Scientific Session, in March 2005. The abstract of their presentation was published in the 1 February Supplement to the *Journal of the American College of Cardiologists* (JACC).

207. Dr. Swerdlow personally presented the research findings of the esophageal temperature monitoring experiment performed on NADINE. A review of Dr. Swerdlow's

**[Second Amended Complaint: Page 53; 1.CT .126]**

presentation was given in the 7 June 2005 JACC. The reviewer, Jamie B. Conti, M.D., F.A.C.C., described Dr. Swerdlow's presentation as follows:

> Finally, Cesario et al. [Citation] (presented by Charles Swerdlow) hypothesized that monitoring of esophageal temperature may detect early temperature rises to prevent esophageal injury. They studied 12 patients using an esophageal temperature probe positioned at the level of the 8-mm ablation tip. Maximum power

> and temperature were 40 to 50 W/50° to 55°. Ablation was terminated when there was an abrupt rise in esophageal temperature (<0.5°). Esophageal temperature rose in 11 patients (92%), although they had no acute or chronic complications. The researchers concluded that esophageal temperature rises abruptly during LA catheter ablation at sites adjacent to the esophagus and that monitoring the esophageal temperature may reduce the risk of LA-esophageal fistula.

208. Plaintiff observes that Dr. Conti describes the basis for this effort as a "hypothesis," and authors as "researchers." On reading this summary and recalling his communications with Drs. Swerdlow and Shivkumar, Plaintiff now came to more fully appreciate just how experimental the procedure that NADINE had been subjected to was and how recklessly and thoughtlessly it was conducted. Plaintiff asserts that when professional colleagues recognize a published work as based on "hypothesis" and the authors as "researchers," one can reasonably conclude that this undertaking was "experimentation for the purpose of pure research."

209. It is noteworthy that Dr. Conti states that Dr. Swerdlow had reported that "they had no acute or chronic complications." Apparently, Dr. Swerdlow didn't think that the loss of NADINE's life after being

surreptitiously subjected to his experimental form of the ablation procedure was "acute" or "chronic" enough to deserve mention. It should also be noted that Drs. Cearío, Shivkumar and Swerdlow, et. al., were only able to accomplish this "slight of hand" by limiting their data to the first twelve patient results. NADINE was apparently patient number 14, and only by excluding her death from the results they chose to report, were Drs. Cearío, Shivkumar and Swerdlow, et. al., able to make the performance claims that they did.

210. Assuming the report by Dr. Conti is accurate, Plaintiff believes that Dr. Swerdlow's telling "less than the whole truth," during his presentation at the *2005 American College of Cardiology Annual Scientific Session*, indicates to Plaintiff that he and Dr. Shivkumar not only deceived NADINE with the "good hands" promise (page 36, *supra*), they did similarly

**[Second Amended Complaint: Page 54; 1.CT .127]**

to their peers in Dr. Swedlow's portrayal of the experimental form of the ablation procedure's effectiveness. Plaintiff can only wonder how many more "NADINEs" might die before the truth is known about what UCLA Doctors have done.

211. But, worst of all, Plaintiff learned that the complication that took NADINE's life was entirely avoidable and that the experimental procedure that she was subjected to was entirely gratuitous and put her "in harm's way" solely for the benefit of the medical research which she was surreptitiously subjected to.

## Experimental Ablation Gratuitously Put NADINE "In Harm's Way"

212. Some time after his last communications with Drs. Swerdlow and Shivkumar, Plaintiff found himself at a loss to understand why it was medically necessary to ablate over NADINE's esophagus during the a cardiac ablation procedure. Since it seemed that Dr. Swerdlow no longer had an interest in helping Plaintiff to understand these issues, Plaintiff continued his study of cardiac catheter ablations and discovered to his shock and horror that the experimental form of the ablation procedure gratuitously put NADINE "in harm's way."

213. Drs. Swerdlow and Shivkumar had omitted from their explanations to Plaintiff that there was no therapeutic need to ablate in the area of the esophagus, namely over the left atrium posterior wall, where damage to the esophagus is most likely. In fact according to the scientific and clinical literature from about 2002 [75] to the time of NADINE's ablation procedure, ablation over the esophagus was considered not only ill-advised, but medically unnecessary. In none of these clinical reports is it recommended that physicians deliberately ablate directly over the esophagus during an ablation procedure, as Drs. Swerdlow and Cesario did to NADINE in their experimental research.

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[75] The earliest reports in 20002 were apparently given as conference presentations before they appeared in the peer-reviewed journals in early 2003.

214. One practitioner warned in a 2003 publication that too little is known about thermal injury to the esophagus and the practitioners are advised not to ablate across the left

**[Second Amended Complaint: Page 55; 1.CT .128]**

atrium posterior wall, but higher in that chamber, nearer the ceiling, to wit:

> Because we were unsure of the exact mode of injury, however, we also modified the IRAAF procedure by moving the lesion line between the upper pulmonary veins to a more superior location in the left atrium.[76]

215. Another 2003 scientific paper also emphasized that *avoiding* atrio-esophageal fistulas meant *not ablating over the esophagus*:

> To prevent injury, *care is taken not to intersect the esophagus with the ablation lines*. This is accomplished by keeping the medial portion of the left encircling ablation (when this is performed

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[76] Doll N, Borger MA, Fabricius A, Stephan S, Gummert J, Mohr FW, Hauss J, Kottkamp H, Hindricks G., "Esophageal perforation during left atrial radiofrequency ablation: Is the risk too high?" *J Thorac Cardiovasc Surg*. 2003 Apr;125(4):836-42, at page 840.

endocardially) far from the midline *and by performing the transverse connecting lesion high in the atrium, opposite to the transverse pericardial sinus*..[77] [Emphasis added].

216. Again and again, the universally recommended method for preventing esophageal injury was "avoidance," as yet another author observed:

> Until we discover the exact mechanism leading to the formation of atrio-esophageal fistula after RF ablation, we have decided to try to reduce the incidence by . . . *connecting the two circles with the transverse line at a higher level to avoid direct heat transmission to the esophagus*.[78] [Emphasis added.]

217. Lastly the *Pappone Scientific Paper* that Drs. Swerdlow and Shivkumar told Plaintiff first advised them of the atrio-esophageal fistula complication, in the April-May 2004 time period, summarized what had apparently become accepted

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[77] Benussi S, Nascimbene S, Calvi S, Alfieri O., "A Tailored Anatomical Approach to Prevent Complications During Left Atrial Ablation." *Ann Thorac Surg*. 2003 Jun;75(6):1979-81, at page 1979.

[78] Sonmez B, Demirsoy E, Yagan N, et al. "A fatal complication due to radiofrequency ablation for atrial fibrillation: atrio-esophageal fistula." *Ann Thorac Surg*. 2003;76:281–283, at page 283.

practice among prudent physicians since at least 2002:

> . . . because atrio-esophageal fistulas have devastating consequences and are often fatal, all possible measures must be taken to avoid this complication.[79]

The *Pappone, Scientific Paper* goes on to warn:

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We recommend that lower generator settings of 50 W and 55° C be used during ablation in the posterior wall to avoid excessively deep lesions and subsequent esophageal injury. *In addition, the transverse posterior line should be placed at the roof, where the atrium tends to be thicker and is not in direct contact with the esophagus.*[80] [Emphasis added.]

218. Most noteworthy in this advice is that there is no mention of ablating over the esophagus of patients while using an anesthesiologists temperature to measure the temperature therein, as Drs. Swerdlow and Cesario did to NADINE. And, since this is the very scientific paper that Drs. Swerdlow and Shivkumar told Plaintiff informed them of the atrio-esophageal fistula complication, and presumably its associated standard of care, under these circumstances to ablate over

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[79] the *Pappone Scientific Paper*, at page 2275.

[80] Ibid., at page 2276.

NADINE's esophagus was gratuitous, and it recklessly endangered her life for the sake of what Drs. Swerdlow and Shivkumar all but admitted to Plaintiff was a poorly conceived medical experiment performed in violation of federal and state statutes and policies.[81]

**Training Dr. Cesario**
**at the Expense of Nadine's Life**

219. As described *supra*, Drs, Swerdlow and Shivkumar agreed to perform NADINE's ablation procedure "as a team." [82]

220. But, during a conversation with Dr. Swerdlow on the Friday before NADINE expired, Dr. Swerdlow informed Plaintiff, for the first time, that an unknown understudy, one Dr. David Cesario, had performed a critical portion of the ablation procedure on NADINE. Dr. Swerdlow revealed to Plaintiff that Dr. Cesario "did the burn" on NADINE under his [Dr. Swerdlow's] "supervision."

221. When Plaintiff demanded to know, referring to Dr. Cesario, and in words almost identical to these: "Who is this guy?" "What was he doing operating on Nadine?" "Nadine never agreed to this." "Nadine and I never interviewed him and we know

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[81] See *Protection of Human Subjects in Experimentation*, at page 11, *supra*.

[82] See *NADINE Selects Her Surgical Team*, at pages 32 though 37, *supra*.

nothing about him."

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Apparently taken aback by Plaintiff's surprised and agitated response to this revelation, Dr. Swerdlow replied dismissively: "how do you think we train doctors." With tears now filling his eyes, Plaintiff countered indignantly, "not by killing Nadine!"

**Nadine Passes Into Eternity on 12 September 2004**

222. In late August, just before the TIA which sent her to Irvine Regional, NADINE began composing an e-mail to Dr. Shivkumar to update him on her post operative progress. But, before she could send it, she expired as a result of the atrio-esophageal fistula complication. NADINE never knew that Dr. Shivkumar had abandoned her in one of her hours of greatest need, so that her need for medical care could be used as an occasion to provide "on-the-job training" for his inexperienced understudy, and that she had been subjected to an unlawful surreptitious medical research experiment which burned a hole through her heart and esophagus, allowing in the air and pathogens which ultimately took her life.

223. On Sunday morning, September 12, 2004, Plaintiff personally reviewed NADINE'S most recent EEG with neurological consultant, Dr. Bruce Cleeremans. With an EEG result indicative of essential brain death, NADINE was discontinued from assistive ventilation with Plaintiff's reluctant consent.

224. Plaintiff stood almost petrified next to NADINE, looking at her lying motionless and expressionless in the Irvine Regional ICU. Plaintiff wanted desperately to pick her up and take her home, but he knew he couldn't. All Plaintiff could manage to do was to stand next to NADINE's bed, and stroke her affectionately, as he watched the EKG monitor showing her heart gradually slowing until it stopped. As Plaintiff watched his wife, NADINE, the love of his life, and soul-mate since college, pass into eternity, he kissed her and promised he would ferret out the cause of her untimely death -- at its most fundamental scientific foundations -- and would see to it that those responsible for any wrongdoing were be held accountable for their acts.

225. With this complaint Plaintiff is keeping that promise he made to his precious, NADINE, as her heart, fatally damaged by the reckless and unlawful conduct of Drs. Cesario, Shivkumar and Swerdlow, beat its last.

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**First Cause of Action**
**Wrongful Death as to Plaintiff, VALER V. SECAREA, JR. (As against all defendants)**

226. Plaintiff incorporates by reference the allegations contained in paragraphs 1 through 225, and each and every party thereof with the same force and effect as though set out at length herein.

227. In or about August 11, 2004, and at all times thereafter up to the time of the death of NADINE on September 12, 2004, defendants, and each of them, so negligently, carelessly, recklessly, wantonly, and without consent, treated, experimented upon, misrepresented, provided such deficient care, monitoring, examination, diagnosis and other medical services so as to directly and proximately cause death to NADINE.

228. Among other things, and not limited to the following, defendants conducted an unlawful, unconsented to experimental form of the ablation procedure upon NADINE in violation of statutes and/or regulations designed to protect the public and NADINE from unauthorized and surreptitious medical experimentation; used medical instrumentation not designed for the specific purpose of performing ablation procedures; encouraged the foreseeable use of the Vital Temp Probe to measure temperatures which were beyond its intended medical design; allowed for a previously undisclosed physician (ghost surgeon) to participate in the ablation procedure for training purposes; failed to properly provide for follow-up in the care and treatment of NADINE; and failed to disclose and to properly treat and diagnose NADINE's fatal atrio-esophageal fistula in a timely manner.

229. At all times herein mentioned, Plaintiff was the spouse of NADINE F. SECAREA, as well as NADINE's successor in interest.

230. As a direct and proximate result of the negligence, carelessness, recklessness, wantonness and

unlawfulness of the defendants, and each of them, and the resulting death, as aforesaid, Plaintiff has sustained severe and serious injury to his person, all to Plaintiff damage in a sum within the jurisdiction of this court and to be shown according to proof.

231. As a direct and proximate result of the conduct of the defendants, and each of

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them, and of the death of NADINE, Plaintiff has been deprived of the society and comfort of NADINE and has been caused the loss of future services, earnings and protection of said spouse, to his great loss and damage in an amount to be shown according to proof.

232. As a direct and proximate result of the conduct of defendants, and each of them, and the resulting death, as aforesaid, Plaintiff has been compelled to incur expenses as well as other special damages, all to the damage of this Plaintiff, in an amount to be shown according to proof, but would not include damages recoverable under Section 377.34.

**Second Cause of Action**
**Survival Action for Lack of Informed Consent**
**(As against Defendants, Dr. Swerdlow, Dr. Shivkumar, Dr. Cesario and UCLA)**

233. Plaintiff incorporates by reference the allegations contained in paragraphs 1 through 234 and each and every party thereof with the same force and

effect as though set out at length herein.

234. From and some time after the said time of employment, defendants Dr. Swerdlow, Dr. Shivkumar, Dr. Cesario and UCLA had and withheld from NADINE and Plaintiff knowledge and material information concerning (1) the almost always fatal atrio-esophageal fistula as a complication to the cardiac catheter ablation procedure; (2) plans to subject NADINE to an experimental form of the ablation procedure; (3) their academic and publishing interests in the experimental form of the ablation procedure they intended to and did surreptitiously perform on NADINE and which influenced and determined the course of NADINE's medical treatment; and (4) using NADINE's need for medical treatment as an opportunity for the unconsented to "on-the-job training" of an inexperienced understudy, Dr. Cesario, during the ablation procedure when NADINE and Plaintiff relied upon the fact that conditional consent had been granted only to Drs. Swerdlow and Shivkumar to personally perform the ablation procedure upon NADINE as her surgical team.

235. Defendants withheld knowledge and material information concerning inherent risks of serious bodily injury to NADINE, the significance of which would have caused her to

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reasonably and objectively refuse to give consent for the cardiac catheter ablation procedure in the manner that

was actually performed on her.

236. Defendants' failure not only to inform NADINE of known risks and to explain those risks in lay terms, but to disclose the intended departure from the course of action to which NADINE had consented and reasonably and objectively expected, as discussed *supra*, breached defendants' duty to disclose all material information under these circumstances.

237. In withholding from NADINE disclosures regarding (1) the significant perils associated with a cardiac catheter ablation procedure, (2) the plan to subject NADINE to an experimental form of the ablation procedure, (3) the academic and publishing interest in said experimentation which influenced and determined the course of NADINE's medical treatment, and (4) the use of NADINE's need for medical treatment as an opportunity to covertly train a previously unknown, inexperienced and unconsented to understudy, Dr. Cesario, to perform some, if not all, of the ablation procedure, NADINE and Plaintiff were subjected to a cynical "bait and switch" scheme which denied critical information on which life-saving informed consent could have been based and that would have materially affected NADINE'S decision to consent to said procedure.

238. In sum, by these acts, Defendants and each of them transformed NADINE from "patient" into "laboratory animal," and made her death not only foreseeable, but almost predictable.

239. In addition, by subjecting NADINE to an entirely different, undisclosed, unknown, unanticipated,

unlawful, and unconsented to course of conduct which was such a radical departure from NADINE's objectively reasonable expectations, it vitiated and annulled her consent to treatment.

240. Consequently, NADINE would have refused consent to the treatment she was subjected to, if she had been fully informed, and given an opportunity to act.

241. Moreover, the experimental form of the ablation procedure was performed in violation of statutes and/or regulations designed to protect the public and NADINE from unauthorized and surreptitious medical experimentation, and required, *inter alia*, a separate and

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specific informed consent. NADINE did not so consent, thus NADINE did NOT consent to the experimental form of the ablation procedure by operation of law.

242. By reason of the foregoing, NADINE was required to employ the services of hospitals, physicians, surgeons, nurses and other professional services and was compelled to incur expenses for ambulance service, medicines, x-rays, and other medical supplies, services and sundries.

243. That as a direct, legal and proximate result of the lack of informed consent, defendants, and each of them, have prevented NADINE from engaging in her usual occupation, thereby sustaining a loss of income both past and future, in an amount as of yet

undeterminable. When said amounts are ascertained, Plaintiff will ask leave of the court to amend this complaint and allege said amounts.

**Third Cause of Action**
**Survival Action for Lack of Informed Consent - Patient Abandonment (As against Defendants, Dr. Swerdlow and Dr. Shivkumar)**

244. Plaintiff incorporates by reference the allegations contained in paragraphs 1 through 243, and each and every party thereof with the same force and effect as though set out at length herein.

245. On or about August 11, 2004, defendants, and each of them, performed what was believed by the NADINE and Plaintiff to be a routine cardiac catheter ablation procedure.

Consent to Surgery was Conditional

246. NADINE'S conditional consent to the ablation treatment required defendants Drs. Swerdlow and Shivkumar to personally perform it as her surgical team.

247. It was the "surgical team" of Drs. Swedlow and Shivkumar to whom NADINE gave her informed consent to surgery, not Dr. Swerdlow as an individual and not Dr. Shivkumar as an individual.

248. Moreover, Drs. Swerdlow and Shivkumar not only accepted this condition, but when NADINE expressed reservations about the ablation procedure,

Dr. Shivkumar said to her

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"stop worrying so much, you're in good hands."

Conditional Consent was Intentionally Violated

249. But, unbnownst to NADINE and Plaintiff at the time, after NADINE was placed under general anesthesia, Dr. Shivkumar, NADINE's UCLA attending physician, left the EP Lab and did not return until more than 5 hours later after an experimental form of the ablation procedure had been performed by physicians to whom NADINE had not given her consent.

250. It was the knowledge and skill of the ablation surgical team of Drs. Swerlow and Shivkumar that enticed NADINE to consent to the course of treatment proposed by them, thus the failure of either of these physicians to attend to NADINE during the ablation procedure was the abandonment of NADINE by the "surgical team" she hired and had the same effect as if both had physically abandoned her, by leaving the EP Lab after she had been anaesthetized.

251. NADINE and Plaintiff were subjected to a cynical "bait and switch" scheme which denied critical information on which life-saving informed consent could have been based and that would have materially affected NADINE'S decision to consent to said procedure

252. These actions were entirely alien to and

beyond the scope of NADINE's objectively reasonable expectations with respect to her conditional consent. Therefore, NADINE's consent to the treatment was vitiated and annulled when the "surgical team" of Drs. Swerdlow and Shivkumar did not perform the ablation procedure as was promised and agreed.

253. In addition, NADINE would have refused consent to the treatment she was subjected to, if she had been fully informed, and given an opportunity to act.

Resulting Damage

254. As a result of the above intentional, unethical, and deceitful act, defendants, and each of them, harmed NADINE by denying her the skill and competence she had relied on and was promised, thereby increasing her risk of developing complications including the fatal atrio-esophageal fistula, among other things, which complication ultimately led to NADINE's demise.

255. Due to the intentional actions of the defendants, and each of them, as aforementioned, NADINE suffered damages as well as the development of additional medical

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problems as a result of defendants' actions, all in an amount as yet unascertainable. Plaintiff will pray leave to amend this complaint accordingly when the true and

exact amount thereof is ascertained by Plaintiff.

256. As a result of the defendants intentional, nonconsensual, malicious, and harmful and offensive treatment of NADINE by way of surgery which was incoonsistent with her conditional consent, NADINE was required to employ the services of hospitals, physicians, surgeons, nurses and other professional services and was compelled to incur expenses for ambulance service, medicines, x-rays, and other medical supplies, services and sundries.

257. That as a direct, legal and proximate result of the aforementioned acts of the defendants, and each of them, the have prevented NADINE from engaging in her usual occupation, thereby sustaining a loss of income both past and future, in an amount as of yet undeterminable. When said amounts are ascertained, Plaintiff will ask leave of the court to amend this complaint and allege said amounts.

**Fourth Cause of Action**
**Survival Action for Battery - Ghost Surgery**
**(As against Defendants, Dr. Swerdlow, Dr. Cesario, Dr. Shivkumar and UCLA)**

258. Plaintiff incorporates by reference the allegations contained in paragraphs 1 through 257, and each and every party thereof with the same force and effect as though set out at length herein.

259. On or about August 11, 2004, defendants, and each of them, performed what was believed by the NADINE and Plaintiff to be a routine cardiac catheter

ablation procedure.

Consent to Surgery was Conditional

260. NADINE'S consent to the ablation procedure was expressly conditioned on defendants Drs. Swerdlow and Shivkumar personally performing it as her surgical ablation team.

261. It was the "surgical team" of Drs. Swedlow and Shivkumar to whom NADINE gave her informed consent to surgery, not Dr. Swerdlow as an individual and not Dr. Shivkumar as an individual.

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262. It was the surgical team of Drs. Swedlow and Shivkumar to whom NADINE gave her informed consent to surgery, not Dr. Swerdlow as an individual and not Dr. Shivkumar as an individual.

263. Moreover, Drs. Swerdlow and Shivkumar not only accepted this condition, but when NADINE expressed reservations about the ablation procedure, Dr. Shivkumar said to her "stop worrying so much, you're in good hands."

Conditional Consent was Intentionally Violated

264. Unbeknownst to NADINE and Plaintiff, at the time were the following intentional acts of the defendants:

a) After NADINE was placed under general

anesthesia, Dr. Shivkumar, NADINE's UCLA attending physician, left the EP Lab and did not return until more than 5 hours later.

b) Rather than NADINE's surgical team performing the ablation procedure as promised to NADINE and Plaintiff prior, Drs. Swerdlow and Shivkumar used NADINE's need for medical treatment as an opportunity to covertly train their previously unknown, inexperienced and unconsented to understudy, Dr. Cesario, to perform some, if not all, of the ablation procedure, in the place and stead of Dr. Shivkumar. This unconsented to substitution of NADINE's surgical team resulted in Dr. Cesario performing critical portions, if not all, of the ablation procedure to which NADINE and Plaintiff did not foresee.

265. It was the knowledge and skill of the surgical team of Drs. Swerlow and Shivkumar that enticed NADINE to consent to the course of treatment proposed by them, thus the failure of either of these physicians to attend to NADINE during the ablation procedure was the abandonment of NADINE by the "surgical team" she hired and had the same effect as if both had physically abandoned her, by leaving the EP Lab after she had been anaesthetized.

266. NADINE and Plaintiff were subjected to a cynical "bait and switch" scheme which denied critical information on which life-saving informed consent could have been based and that would have materially affected NADINE'S decision to consent to said procedure

267. These actions were entirely alien to and

beyond the scope of NADINE's

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objectively reasonable expectations with respect to her conditional consent. Therefore, NADINE's consent to the treatment was vitiated and annulled when the "surgical team" of Drs. Swerdlow and Shivkumar did not perform the ablation procedure as was promised and agreed.

268. In addition, NADINE would have refused consent to the treatment she was subjected to, if she had been fully informed, and given an opportunity to act.

Resulting Damage

269. In sum, by these acts, Defendants and each of them transformed NADINE's ablation procedure from medical treatment intended to benefit NADINE into a "on-the-job training" intended to benefit unknown understudy Dr. Cesario, to NADINE's detriment.

270. As a result of the above unlawful, intentional, unethical, and deceitful acts, defendants, and each of them, harmed NADINE by not only substantially increasing her risk of developing the fatal atrio-esophageal fistula complication, among other things, which complication ultimately led to NADINE's demise, but by performing acts to which she did not give her informed consent.

271. Due to the intentional actions of the

defendants, and each of them, as aforementioned, NADINE suffered damages as well as the development of additional medical problems as a result of defendants' actions, all in an amount as yet unascertainable. Plaintiff will pray leave to amend this complaint accordingly when the true and exact amount thereof is ascertained by Plaintiff.

272. As a result of the defendants intentional, nonconsensual, malicious, and harmful and offensive treatment of NADINE by way of the unconsented to surgery performed by Dr. Cesario; affirmed by Drs. Swerdlow and Shivkumar, NADINE was required to employ the services of hospitals, physicians, surgeons, nurses and other professional services and was compelled to incur expenses for ambulance service, medicines, x-rays, and other medical supplies, services and sundries.

273. That as a direct, legal and proximate result of the aforementioned acts of the defendants, and each of them, the have prevented NADINE from engaging in her usual occupation, thereby sustaining a loss of income both past and future, in an amount as of yet

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undeterminable. When said amounts are ascertained, Plaintiff will ask leave of the court to amend this complaint and allege said amounts.

**Fifth Cause of Action**
**Survival Action for Battery - Covert Medical Experimentation (As against Defendants, Dr. Swerdlow, Dr. Shivkumar, Dr. Cesario and UCLA)**

274. Plaintiff incorporates by reference the allegations contained in paragraphs 1 through 273, and each and every party thereof with the same force and effect as though set out at length herein.

275. On or about August 11, 2004, defendants, and each of them, performed what was believed by the NADINE and Plaintiff to be a routine cardiac catheter ablation procedure.

276. Unbeknownst to NADINE and Plaintiff at the time were the following intentional acts:

a) Defendants, and each of them performed an experimental form of the ablation procedure upon NADINE, using her need for medical treatment as an opportunity to surreptitiously engage in a dangerous and purely speculative course of conduct that was neither known to, nor consented to, by NADINE or Plaintiff, and which put NADINE at special risk in order to satisfy the requirements of the experimental research protocol;

b) Defendants, and each of them concealed their academic and publishing interest in the experimental form of the ablation procedure from NADINE and Plaintiff;

c) Defendants, and each of them were unduly influenced by their personal interests in publishing the

research results of the experimental form of the ablation procedure. This consideration determined the course of NADINE's medical treatment, to her detriment, in that Drs. Cesario and Swedlow gratuitously ablated over NADINE's esophagus to accommodate their experimental and investigational efforts, thereby placing NADINE "in harm's way" for no legitimate therapeutic purpose.

277. The experimental form of the ablation procedure was performed in violation of

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statutes and/or regulations designed to protect the public and NADINE from unauthorized and surreptitious medical experimentation, and required, *inter alia*, a separate and specific informed consent. NADINE did not so consent, thus NADINE did NOT consent to the experimental form of the ablation procedure by operation of law.

278. Moreover, the medical experimentation complained of herein was not only unlawful, but an extreme and radical departure from and were outside the scope of the objectively reasonable expectations of the course of treatment to which NADINE gave her informed consent. .

279. As a result of the above unlawful, intentional, unethical, and deceitful acts, defendants, and each of them, harmed NADINE by substantially increasing her risk of developing the fatal atrio-esophageal fistula complication, among other things,

which complication ultimately led to NADINE's demise.

280. NADINE's consent was vitiated and annulled when an unnecessary and recklessly dangerous surreptitious experimental component to the ablation procedure, which failed to perform as expected, was injected into an otherwise routine procedure.

281. NADINE's consent was vitiated and annulled when Drs. Swerdlow and Shivkumar withheld disclosure of their academic and publication interests in said experiment and permitted these considerations to influence and determine the course of NADINE's medical treatment.

282. In sum, by these acts, Defendants and each of them transformed NADINE from "patient" into "laboratory animal," thereby subjecting her to an entirely undisclosed, unknown, unanticipated, unlawful, and unconsented to course of conduct that made her death not only foreseeable, but almost predictable.

283. In addition, NADINE would have refused consent to the treatment she was subjected to, if she had been fully informed, and given an opportunity to act.

284. Due to the intentional actions of the defendants, and each of them, as aforementioned, NADINE suffered damages as well as the development of additional medical problems as a result of defendants' actions, all in an amount as yet unascertainable. Plaintiff will

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pray leave to amend this complaint accordingly when the true and exact amount thereof is ascertained by Plaintiff.

285. As a result of the defendants intentional, nonconsensual, malicious, and harmful and offensive treatment of NADINE by way of the unconsented to a experimental form of ablation procedure that was unlawful and substantially different from the treatment to which NADINE consented to, NADINE was required to employ the services of hospitals, physicians, surgeons, nurses and other professional services and was compelled to incur expenses for ambulance service, medicines, x-rays, and other medical supplies, services and sundries.

286. That as a direct, legal and proximate result of the aforementioned acts of the defendants, and each of them, the have prevented NADINE from engaging in her usual occupation, thereby sustaining a loss of income both past and future, in an amount as of yet undeterminable. When said amounts are ascertained, Plaintiff will ask leave of the court to amend this complaint and allege said amounts.

**Sixth Cause of Action**
**Survival and Individual Action for Fraud - Ghost Surgery (As against Defendants, Dr. Swerdlow, Dr. Shivkumar, Dr. Cesario and UCLA)**

287. Plaintiff incorporates by reference the allegations contained in paragraphs 1 through 288, and

each and every party thereof with the same force and effect as though set out at length herein.

288. On or about September of 2003 and beyond, NADINE and Plaintiff researched and interviewed Drs. Swerdlow and Shivkumar as candidates to constitute the two physician cardiac catheter ablation team.

289. The skill, experience and competence of the surgical team who would perform NADINE's ablation procedure were of utmost importance to NADINE and Plaintiff. Thus, as a condition precedent to this surgical procedure, NADINE expressly identified the members of the surgical team to whom she would give her consent to treatment.

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The Representations by Drs. Swerdlow and Shivkumar

290. During the interview process, as well as follow-up communications, Drs. Swerdlow and Shivkumar held themselves out to be not only exceptionally qualified to perform the elective cardiac ablation procedure, but experienced at working together "as a team." During this interview and communication process, NADINE stipulated that her consent to the ablation procedure was dependent on Drs. Swerdlow and Shivkumar's personally perform it together, as her surgical team. This requirement constituted NADINE's conditional consent to the ablation procedure. Defendants, and each of them, ostensibly assured NADINE and Plaintiff that they alone would be

performing the ablation procedure. Defendants, and each of them, knew this fact to be material to NADINE and Plaintiff's decision to hire defendants to perform the procedure.

291. In sum, NADINE's consent to surgery was not given to "the world of physicians at large," it was given exclusively and solely to the "surgical team" of Drs. Swerdlow and Shivkumar.

292. Yet, from time of hire and beyond, and although defendants and NADINE formed a fiduciary relationship, at some time, from the time of hire to the time of the ablation procedure, defendants, and each them, did so knowingly or with reckless disregard for the rights of NADINE and Plaintiff, falsely represent to NADINE and Plaintiff the facts, as aforementioned, knowing that such facts to be untrue, so as to induce reliance and continue to keep NADINE as a patient and to undergo the ablation procedure so that Defendants could surreptitiously pursue their ulterior motive of using NADINE's living body to provide an opportunity for "on-the-job training" for understudy Dr. Cesario – to the detriment of NADINE.

Non-Disclosure and Misrepresentation of Material Facts by Defendants

293. Unbeknownst to NADINE and Plaintiff, defendants, and each of them, did intentionally and knowingly or with reckless disregard for the rights of NADINE and Plaintiff, conceal from NADINE and Plaintiff, even during conversations had the evening

before and the morning of NADINE's ablation procedure, that they in fact, would not be performing the ablation surgery as a team as agreed, but instead intended to and did transform NADINE's ablation procedure from medical treatment intended to benefit NADINE into "on-the-job

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training" intended to benefit understudy Dr. Cesario. During the ablation procedure Dr. Cesario surreptitiously assumed the role of ablation team electrophysiologist in the place and stead of Dr. Shivkumar. This unconsented to substitution of surgical teams resulted in Dr. Cesario performing a critical portion, if not all, of the ablation procedure to which NADINE and Plaintiff did not foresee or consent.

294. Plaintiff alleges that the substitution of surgical teams and ghost surgery complained of herein was a dramatic and radical departure from and were outside the scope of the objectively reasonable expectations of the course of treatment to which NADINE gave her informed consent.

295. The alleged ghost surgery was performed at a time when NADINE was under anesthesia and was incapacitated and unable to speak for herself.

296. At no time while NADINE was incapacitated and unable to speak for herself, did Defendants contact Plaintiff to inquire about the substitution of surgical teams herein described.

297. But, Defendants knew or should have

known that NADINE and Plaintiff made the ablation decision together, so they also knew that Plaintiff would have refused to allow to any revision of the conditions NADINE and Plaintiff so carefully fashioned.

298. These actions were entirely alien to and beyond the scope of NADINE's objectively reasonable expectations and conditional consent to surgery. NADINE's consent was vitiated and annulled when Drs. Swerdlow and Shivkumar withheld disclosure of their intent to use NADINE's ablation procedure as a pretext to train their understudy Dr. Cesario and permitted this considerations to influence and determine the course and quality of NADINE's medical care.

Intent to Induce Reliance and to Defraud

299. Because fiduciary duty is a continuing obligation, Defendants' duty to disclose material information relevant to NADINE's medical treatment persisted for so long as NADINE was in Defendants' care. Moreover, as stated *supra*, (at page ?), Drs. Swerdlow and Shivkumar assumed the duty of candid disclosure to both NADINE and Plaintiff, when NADINE had informed them that the ablation treatment was a joint decision.

300. At all times applicable to the unconsented to substitution of surgical teams and

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ghost surgery complained of herein, NADINE and

Plaintiff were subjected to a classic "bait and switch" scheme by Defendants. As noted supra, Drs. Swerdlow and Shivkumar

301. At all times applicable to the unconsented to substitution of surgical teams and ghost surgery complained of herein, Defendants and each of them acted with either deliberate intent to violate or with reckless disregard for the legal rights of NADINE and Plaintiff in order to keep NADINE and Plaintiff ignorant of the true nature of Defendants' intentions and to induce reliance on the false representations and omissions, so as to prevent NADINE and Plaintiff from discovering and escaping from Defendants' plan to transform NADINE's ablation procedure from medical treatment intended to benefit NADINE into "on-the-job training" intended to benefit understudy Dr. Cesario.

302. At all times applicable to the unconsented to substitution of surgical teams and ghost surgery complained of herein, Defendants and each of them acted with either deliberate intent to violate or with reckless disregard for the legal rights of NADINE and Plaintiff in order to keep NADINE and Plaintiff ignorant of the true nature of Defendants' intentions and to induce reliance on the false representations and omissions, so as to prevent NADINE and Plaintiff from discovering and escaping from Defendants' plan to subject NADINE to heightened risks of physical harm and the actual physical harm and death that was ultimately inflicted on NADINE at the hands of Defendants in pursuit of their surreptitious purpose.

Reliance by NADINE and Plaintiff

303. NADINE and Plaintiff relied on the representations of Drs. Swerdlow and Shivkumar that they would treat NADINE as they had promised, operating "as a team," and using their extensive experience treating cardiac arrhythmia and working together to effect a cure for NADINE's medical condition.

304. NADINE's conditional consent to the ablation procedure was premised almost entirely on the promises of Drs. Swerdlow and Shivkumar that they would personally perform the ablation procedure, as her surgical team.

305. NADINE and Plaintiff believed these false statements, concealment and non-disclosures, and NADINE was thereby deceived into consenting to the ablation procedure in

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reliance on Defendants' subterfuge.

306. In addition, because the skill, experience and competence of the surgical team who would perform NADINE's ablation procedure were of utmost importance to NADINE and Plaintiff, NADINE would have refused consent to the treatment she was subjected to, if either NADINE or Plaintiff had been fully informed, and given an opportunity to act.

Resulting Damage

307. The results of Dr. Shivkumar's and Dr. Swerdlow's abandonment of NADINE and Dr. Cesario's unconsented to intrusion into NADINE's medical care was that:

a) NADINE was deprived of the benefits of Dr. Shivkumar's considerable experience, ability, skill and knowledge.

b) NADINE was deprived of the benefits of the considerable experience, ability, skill and knowledge of the team of Drs. Swerdlow and Shivkumar.

c) NADINE was deprived of the benefits of competent skillful medical care when Dr. Cesario substituted his unsteady, unknowledgeable, untrained hands for those of the experienced Dr. Shivkumar.

d) NADINE was deprived of the benefits of the quality medical care she and Plaintiff had arranged for and was instead dispensed a level of care that was far beneath her reasonable expectation and informed consent.

e) NADINE was subjected to risks and dangers associated with Dr. Cesario's inexperience and ignorance to which NADINE was neither informed of or consented to.

f) Plaintiff was deprived of the opportunity to save his wife's life as he would have reminded NADINE that they had been advised by Drs. Swerdlow and Shivkumar that, all other things being equal, her outcome from an ablation procedure is primarily dependent on the skill of the electrophysiologist performing it.

308. In doing the acts herein alleged, defendants, and each of them, acted with oppression, fraud and malice, with full knowledge of the falsity of the representations which induced reliance on the part of NADINE and Plaintiff.

309. As a result of the foregoing, the proximate result of the acts herein alleged was

**[Second Amended Complaint: Page 73; 1.CT .146]**

that NADINE suffered an atrio-esophageal fistula which caused great bodily harm to her person, including death on September 12, 2004. Each of the acts alleged herein were done with a wanton, reckless disregard for the rights of the NADINE and Plaintiff and with the full knowledge that NADINE could or would be harmed as a result of said acts.

310. In sum, by these acts, Defendants and each of them transformed NADINE from "patient" into "laboratory animal," thereby subjecting her to an entirely undisclosed, unknown, unanticipated and unconsented to course of conduct that made her death not only foreseeable, but almost predictable, and in so doing, deprived Plaintiff of the care and companionship of his wife, NADINE.

311. By reason of the foregoing, NADINE was required to employ the services of hospitals, physicians, surgeons, nurses and other professional services and was compelled to incur expenses for ambulance service, medicines, x-rays, and other medical supplies, services and sundries in an amount as yet unascertained. When

said amounts are ascertained, Plaintiff will ask leave of the court to amend this complaint and allege said amounts.

312. That as a direct, legal and proximate result of the aforementioned acts of the defendants, and each of them, they have prevented NADINE from engaging in her usual occupation, thereby sustaining a loss of income both past and future, in an amount as of yet undeterminable. When said amounts are ascertained, Plaintiff will ask leave of the court to amend this complaint and allege said amounts.

**Seventh Cause of Action**
**Survival and Individual Action for Fraud - Medical Experimentation (As against Defendants, Drs. Swerdlow, Shivkumar, and UCLA)**

313. Plaintiff incorporates by reference the allegations contained in paragraphs 1 through 312, and each and every party thereof with the same force and effect as though set out at length herein.

314. On or about September of 2003 and beyond, NADINE and Plaintiff researched and interviewed Drs. Swerdlow and Shivkumar as candidates to constitute the two physician

**[Second Amended Complaint: Page 74; 1.CT .147]**

cardiac catheter ablation team.

The Representations by Drs. Swerdlow and Shivkumar

315. During the interview process, as well as follow-up communications, defendants held themselves out to be exceptionally qualified to perform the elective cardiac ablation procedure.

316. In addition, NADINE and Plaintiff sought assurances that the procedure would be performed in accordance with the best community standards, as provided in the medical, scientific and clinical literature contemporaneous with NADINE's ablation procedure and that they would inform NADINE and Plaintiff of developments relevant to NADINE's treatment.

317. Drs. Swerdlow and Shivkumar, both clinical professors of medicine at UCLA assured NADINE and Plaintiff that they kept abreast of the latest developments of the field of cardiac arrhythmia and its treatment.

318. Defendants, and each of them, knew this fact to be material to NADINE and Plaintiff's decision to hire defendants to perform the procedure and that NADINE's consent to surgery was conditioned on this promise.

319. Yet, from time of hire and beyond, and although defendants and NADINE formed a fiduciary relationship, at some time, from the time of hire to the time of the ablation procedure, defendants, and each them, did so knowingly and falsely represent to NADINE and Plaintiff the facts, as aforementioned, knowing that such facts to be untrue, so as to induce reliance and continue to keep NADINE as a patient and

to undergo the ablation procedure so that Defendants could surreptitiously pursue their ulterior motive of transforming NADINE from "patient" into "laboratory animal" for purposes of pursuing Defendants' medical experimentation.

Non-Disclosure and Misrepresentation of Material Facts by Defendants

320. Unbeknownst to NADINE and Plaintiff, Defendants, and each of them, did intentionally and knowingly misrepresent or conceal from NADINE and Plaintiff, even during conversations had the evening before and the morning of NADINE's ablation procedure that:

a) The existence and information about of the almost always fatal atrio-esophageal fistula complication was known to Defendants, but had been withheld from

**[Second Amended Complaint: Page 75; 1.CT .148]**

NADINE;

b) Defendants would not be performing an ablation procedure inaccordance with community standards as provided for in the medical, scientific and clinical literature, with respect to avoidance of the atrio-esophageal fistula complication, but instead, intended to subject NADINE in a speculative experimental form of the ablation procedure without her knowledge or

consent;

c) Defendants, and each of them, in order to satisfy the requirements of the experimental ablation procedure, would use NADINE's need for medical treatment as a pretext to surreptitiously engage in an unlawful, dangerous and purely speculative course of conduct, which called for ablating directly over NADINE's esophagus, and which would put NADINE at special risk for the atrio-esophageal fistula complication;

d) Defendants' had a personal academic and publishing interest in the experimental form of the ablation procedure they would perform on NADINE;

e) Defendants, and each of them were unduly influenced by their personal interests in publishing the results of the experimental form of the ablation procedure and allowed this consideration to determine the course of NADINE's medical treatment in order to accommodate their experimental needs, all to the detriment of NADINE;

f) Defendants were using the Vital Signs Probe in an investigational and experimental setting without required approvals;

g) While the medical, scientific and clinical literature on the subject of the atrio-esophageal fistula complication since the year 2001, cautioned and advised to refrain from ablating over the esophagus, Defendants intended to ablate directly over and into NADINE's esophagus in order to accommodate their experimental efforts.

321. These actions were entirely alien to and beyond the scope of NADINE's objectively reasonable

expectations and conditional consent to surgery. NADINE's consent was vitiated and annulled when Drs. Swerdlow and Shivkumar withheld disclosure of their intent to use NADINE's ablation procedure as a pretext to subject her to an investigational and experimental from of the ablation procedure.

**[Second Amended Complaint: Page 76; 1.CT .149]**

322. Plaintiff alleges that the medical experimentation complained of herein was a extreme and radical departure from and were outside the scope of the objectively reasonable expectations of the course of treatment to which NADINE gave her informed consent.

323. The alleged medical experimentation was performed at a time when NADINE was under anesthesia and was incapacitated and unable to speak for herself.

324. At no time while NADINE was incapacitated and unable to speak for herself, did Defendants contact Plaintiff to inquire about performing the experimental form of the ablation procedure herein described.

325. But, Defendants knew that NADINE and Plaintiff made the ablation decision together, so they also knew or should have known that Plaintiff would have refused to allow NADINE to be subjected to a medical research experiment. Plaintiff would have demanded that NADINE be revived so the entire ablation procedure question could be reconsidered in

light of the newly disclosed revelations.

Intent to Induce Reliance and to Defraud

326. Because fiduciary duty is a continuing obligation, Defendants' duty to disclose material information relevant to NADINE's medical treatment persisted for so long as NADINE was in Defendants' care.

327. At all times applicable to the unconsented-to medical experimentation complained of herein, NADINE and Plaintiff were subjected to a classic "bait and switch" scheme by Defendants, where Defendants promised to apply their considerable skill, knowledge and expertise to the interests of NADINE's medical care, which included precautions for avoiding the atrio-esophageal fistula complication, but instead used NADINE's need for medical treatment as an opportunity to pursue their own interests in publishing the results of their surreptitious medical experimentation.

328. At all times applicable to the unconsented-to medical experimentation complained of herein, Defendants and each of them acted with either deliberate intent to violate or with reckless disregard for the legal rights of NADINE and Plaintiff in order to keep NADINE and Plaintiff ignorant of the true nature of Defendants' intentions and to induce reliance on the false

**[Second Amended Complaint: Page 77; 1.CT .150]**

representations and omissions, and to prevent NADINE and Plaintiff from discovering and escaping from Defendants' plan to transform her ablation procedure from medical treatment intended to benefit NADINE into a medical experiment intended to satisfy the undisclosed academic publishing interests of Defendants.

329. At all times applicable to the unconsented-to medical experiment complained of herein, Defendants and each of them acted with either deliberate intent to violate or with reckless disregard for the legal rights of NADINE and Plaintiff in order to keep NADINE and Plaintiff ignorant of the true nature of Defendants' intentions and to induce reliance on the false representations and omissions, so as to prevent NADINE and Plaintiff from discovering and escaping from Defendants' plan to subject NADINE to heightened risks of physical harm and the actual physical harm and death that was ultimately inflicted on NADINE at the hands of Defendants in pursuit of their surreptitious purpose.

Reliance by NADINE and Plaintiff

330. NADINE and Plaintiff relied on the representations of Drs. Swerdlow and Shivkumar that they would treat NADINE as they had promised, operating "as a team," and using their extensive experience treating cardiac arrhythmia and working together to effect a cure for NADINE's medical condition.

331. NADINE's informed consent to the ablation procedure was premised and conditioned on Drs. Swerdlow and Shivkumar using he latest medical and scientific knowledge to treat her cardiac arrhythmia, which included precautions for avoiding the atrio-esophageal fistula complication.

332. NADINE and Plaintiff believed these false statements, concealment and non-disclosures, and NADINE was thereby deceived into consenting to the ablation procedure in reliance on Defendants' subterfuge.

333. In addition, NADINE would have refused consent to the treatment she was subjected to, if she had been fully informed, and given an opportunity to act.

Resulting Damage

334. The result of Defendants performing the experimental form

**[Second Amended Complaint: Page 78; 1.CT .151]**

of the ablation procedure on NADINE was that:

a) NADINE was deprived of the benefits of care which was prudent and appropriate to her condition;

b) Defendants, and each of them were unduly influenced by their personal interests in publishing the results of the experimental form of the ablation

procedure. This consideration determined the course of NADINE's medical treatment, to her detriment, in that Drs. Cesario and Swedlow gratuitously ablated over and into NADINE's esophagus to accommodate their experimental and investigational efforts, thereby placing NADINE "in harm's way" for no legitimate therapeutic purpose;

c) NADINE was deprived of the benefit of laws intended to protect her in that the experimental form of the ablation procedure was in violation of statutes and/or regulations designed to protect the public and NADINE from unauthorized and surreptitious medical experimentation;

d) NADINE was deprived of the benefits of the quality medical care she and Plaintiff had arranged for and was instead dispensed a level of care that was far beneath her reasonable expectation and informed consent;

e) NADINE was subjected to risks and dangers associated an untested, unproven and speculative procedure she was neither informed of or consented to;

f) NADINE was deprived of the application of latest medical and scientific knowledge to treat her cardiac arrhythmia which, since at least 2001, advised that care should be taken to refrain from ablating over the esophagus, and which if followed, would have completely avoided the atrio-esophageal fistula complication that took NADINE's life.

g) Plaintiff engineer was deprived of the opportunity to save his wife's life, as he had the

requisite scientific background to understand the reckless disregard for NADINE's health and safety that the experimental form of the ablation procedure represented, and that the proposed actions by Drs. Swerdlow and Shivkumar represented such extreme ignorance that NADINE and Plaintiff would be best advised to seek alternative medical care for NADINE's cardiac ailment.

**[Second Amended Complaint: Page 79; 1.CT .152]**

335. In doing the acts herein alleged, defendants, and each of them, acted with oppression, fraud and malice, with full knowledge of the falsity of the representations which induced reliance on the part of NADINE and Plaintiff.

336. As a result of the foregoing, the proximate result of the acts herein alleged was that NADINE suffered an atrio-esophageal fistula which caused great bodily harm to her person, including death on September 12, 2004. Each of the acts alleged herein were done with a wanton, reckless disregard for the rights of NADINE and Plaintiff and with the full knowledge that Nadine could or would be harmed as a result of said acts.

337. In sum, by these acts, Defendants and each of them transformed NADINE from "patient" into "laboratory animal," thereby subjecting her to an entirely undisclosed, unknown, unanticipated and unconsented to course of conduct that made her death not only foreseeable, but almost predictable and in so

doing, deprived Plaintiff of the care and companionship of his wife, NADINE.

338. By reason of the foregoing, NADINE was required to employ the services of hospitals, physicians, surgeons, nurses and other professional services and was compelled to incur expenses for ambulance service, medicines, x-rays, and other medical supplies, services and sundries in an amount as yet unascertained. When said amounts are ascertained, Plaintiff will ask leave of the court to amend this complaint and allege said amounts.

339. That as a direct, legal and proximate result of the aforementioned acts of the defendants, and each of them, they have prevented NADINE from engaging in her usual occupation, thereby sustaining a loss of income both past and future, in an amount as of yet undeterminable. When said amounts are ascertained, Plaintiff will ask leave of the court to amend this complaint and allege said amounts.

**[Second Amended Complaint: Page 80; 1.CT .153]**

**Eighth Cause of Action**
**Survival Action for Negligence Per Se**
**(As against Defendants Dr. Swerdlow, Dr. Shivkumar, Dr. Cesario, UCLA, Vital Signs, Inc.)**

340. Plaintiff incorporates by reference the allegations contained in paragraphs 1 through 339, and each and every party thereof with the same force and

effect as though set out at length herein.

341. Defendants, and each of them, are negligent per se, directly and/or vicariously, and are thus liable for the death of NADINE and Plaintiff's injuries and damages.

342. As to UCLA, as a government entity, at all times herein mentioned Government Code § 815.6 provides that a public entity is liable for an injury proximately caused by its failure to discharge a mandatory duty designed to protect against the risk of a particular kind of injury.

343. At all times herein mentioned, it was UCLA's obligation to protect NADINE against the harm that came to her as a result of the unlawful medical experimentation she was subjected to, according to the requirements of statutes and/or regulations designed to protect the public and NADINE from unauthorized and surreptitious medical experimentation.

344. At all times herein mentioned, UCLA failed in that obligation and must therefore bear the liability of Government Code § 815.6.

345. At all times herein mentioned, UCLA operated in the dual capacity of service provider and seller to the public of medical paraphernalia of almost every description.

346. Defendant, VITAL SIGNS while manufacturing, designing, assembling, compounding, testing, inspecting, packaging, labeling, fabricating, constructing, analyzing, distributing, servicing, merchandising, recommending, advertising, promoting, marketing, supplying and selling Vital Temp Probes to

be sold to, and used by, healthcare providers, such as Drs. Swerdlow, Shivkumar and Cesario and UCLA for the benefit of their patients, such as NADINE, did violate statutes and/or regulations designed to protect the public and NADINE from unauthorized and surreptitious medical experimentation, as well as other federal and/or state statutes and/or regulations that were intended to protect a class of persons, including

**[Second Amended Complaint: Page 81; 1.CT .154]**

NADINE, and that were intended to protect the interest of the public and NADINE. When facts relating to said additional statutes become known, Plaintiff will ask leave of this Court to amend this complaint to reflect such other and further statutes and/or regulations.

347. The purpose of such statutes and/or regulations is to protect the interests of the public, and NADINE, against the kind of harm that resulted from defendants use of the Vital Temp Probe and under the experimental setting encouraged by all defendants, and each of them.

348. UCLA Doctors were engaged in an investigational study whose purpose it was to show that the Vital Signs Probe could be utilized to detect a particular kind of temperature rise in the esophagus whose character is sufficient to cause the kind of thermal damage which they theorized leads to atrio-esophageal fistula formation.

349. Without her knowledge or consent, NADINE was subjected to a medical experiment

involving the Vital Signs Probe, a study which was subject to FDA regulation under the FDCA.

350. The Vital Signs Probe was neither designed nor marketed as a tool to detect a temperature rise in the esophagus sufficient to cause thermal damage leading to atrio-esophageal fistula formation.

351. The Vital Signs Probe, as used by defendants, could not perform the function of detecting a temperature rise in the esophagus sufficient to cause thermal damage leading to atrio-esophageal fistula formation.

352. Defendants ablated over and into NADINE'S esophagus, relying on the Vital Signs Probe to warn of a temperature rise in the esophagus sufficient to cause thermal damage leading to atrio-esophageal fistula formation.

353. The Vital Signs Probe failed to warn Defendants of a temperature rise in the esophagus sufficient to cause thermal damage leading to atrio-esophageal fistula formation and NADINE consequently suffered an atrio-esophageal fistula which took her life.

354. In addition, Vital Signs withheld from the marketplace crucial information regarding the performance limitations of their device making its use to measure temperature beyond its design capabilities not only foreseeable, but almost predictable.

**[Second Amended Complaint: Page 82; 1.CT .154]**

355. NADINE'S death was a direct and proximate result of the violation of statutes and/or

regulations designed to protect the public and NADINE from unauthorized and surreptitious medical experimentation.

356. NADINE suffered damages in an amount to be shown according to proof.

357. By reason of the foregoing, NADINE was required to employ the services of hospitals, physicians, surgeons, nurses and other professional services and was compelled to incur expenses for ambulance service, medicines, x-rays, and other medical supplies, services and sundries in an amount as yet unascertained. When said amounts are ascertained, Plaintiff will ask leave of the court to amend this complaint and allege said amounts.

358. That as a direct, legal and proximate result of the aforementioned actions of the defendants, and each of them, they have prevented NADINE from engaging in her usual occupation, thereby sustaining a loss of income both past and future, in an amount as of yet undeterminable. When said amounts are ascertained, Plaintiff will ask leave of the court to amend this complaint and allege said amounts.

**Ninth Cause of Action**
**Survival Action for Product Liability - Negligence (As against Defendant, Vital Signs, Inc., Dr. Swerdlow, Dr. Shivkumar, UCLA)**

359. Plaintiff incorporates by reference the allegations contained in paragraphs 1 through 358, and each and every party thereof with the same force and

effect as though set out at length herein.

360. At all times herein mentioned, VITAL SIGNS, INC. was engaged in the business of manufacturing, designing, assembling, compounding, testing, inspecting, packaging, labeling, fabricating, constructing, analyzing, distributing, servicing, merchandising, recommending, advertising, promoting, marketing, supplying and selling said Vital Temp Monitoring Devices, and all component parts thereof, including but not limited to the said VITAL TEMP PROBE (as previously described), and all component parts thereof, for sale to and use by members of the medical profession knowing that such probes are to be used upon patients, of which NADINE

**[Second Amended Complaint: Page 83; 1.CT .156]**

was a part.

361. At all times herein mentioned, defendants, and each of them, knew, or in the exercise of ordinary and reasonable care should have known, that the said Vital Temp Probe was a product of such a nature that if it was not properly manufactured, designed, assembled, compounded, tested, inspected, packaged, labeled, fabricated, constructed, analyzed, distributed, serviced, merchandised, recommended, advertised, promoted, marketed and sold, for the use and purpose for which it was intended, it was likely to injure the person or persons by whom it was used for.

362. The defendants, and each of them, so negligently and carelessly manufactured, designed,

assembled, compounded, tested or failed to test, inspected or failed to inspect, packaged, labeled, fabricated, constructed, analyzed, distributed, serviced, merchandised, recommended, advertised, promoted, marketed and sold said Vital Temp Monitoring Devices, and all component parts thereof, including but not limited to the said VITAL TEMP PROBE, and all component parts thereof, so that it was in a dangerous and defective condition, and unsafe for the use and purpose for which it was intended and/or used, as was foreseeable as used by co-defendants, and each of them.

363. As a result of the use of the VITAL TEMP PROBE for the purpose for which it was not intended and/or for a use reasonably foreseeable, NADINE was caused to suffer complications during cardiac ablation, ultimately leading to her death on September 12, 2004.

364. In addition, Vital Signs withheld from the marketplace crucial information regarding the performance limitations of their device making its use to measure temperature beyond its design capabilities not only foreseeable, but almost predictable.

365. At all times herein mentioned, UCLA operated in the dual capacity of service provider and seller to the public of medical paraphernalia of almost every description.

366. Moreover, in their dual capacity role, UCLA Defendants were not acting as "service providers" or "passive users" of the medical devices when they engaged in the surreptitious experimentation on NADINE with the Vital Signs Probe. Instead they stood in the shoes of "designers," "repackagers,"

"relabelers," "remanufacturers"(21 CFR 820.3(w)), and

**[Second Amended Complaint: Page 84; 1.CT .157]**

"distributors" of a new and heretofore unknown device, namely Vital signs Probe qua "Vital Signs atrio-esophageal fistula prevention tool." At least 14 patients were experimented on with this "new device," thus it was actually or constructively placed into the stream of commerce by defendants without approval of the FDA for this use.

367. As a result of the aforesaid injuries, Plaintiff has been generally damaged in a sum in excess of the jurisdictional limits of this court.

368. By reason of the foregoing, NADINE was required to employ the services of hospitals, physicians, surgeons, nurses and other professional services and was compelled to incur expenses for ambulance service, medicines, x-rays, and other medical supplies, services and sundries in an amount as yet unascertained. When said amounts are ascertained, Plaintiff will ask leave of the court to amend this complaint and allege said amounts.

369. That as a direct, legal and proximate result of the aforementioned acts of the defendants, and each of them, they have prevented NADINE from engaging in her usual occupation, thereby sustaining a loss of income both past and future, in an amount as of yet undeterminable. When said amounts are ascertained, Plaintiff will ask leave of the court to amend this complaint and allege said amounts.

**Tenth Cause of Action**
**Survival Action for Strict Products Liability**
**(As against Defendant, Vital Signs, Inc., Dr. Swerdlow, Dr. Shivkumar, UCLA)**

370. Plaintiff incorporates by reference the allegations contained in paragraphs 1 through 369, and each and every party thereof with the same force and effect as though set out at length herein.

371. The defendants, and each of them, so negligently and carelessly manufactured, designed, assembled, compounded, tested or failed to test, inspected or failed to inspect, packaged, labeled, fabricated, constructed, analyzed, distributed, serviced, merchandised, recommended, advertised, promoted, marketed and sold said Vital Temp Monitoring Devices, and all component parts thereof, including but not limited to the said VITAL TEMP PROBE, and

**[Second Amended Complaint: Page 85; 1.CT .158]**

all component parts thereof, so that it was in a dangerous and defective condition, and unsafe for the use and purpose for which it was intended and/or used, as was foreseeable as used by co-defendants, and each of them.

372. Defendants, and each of them, knew that said VITAL TEMP PROBE was to be purchased and used without inspection for defects by NADINE and all other patients.

373. The VITAL TEMP PROBE was unsafe for

its intended, or reasonably foreseeable use, by reason of defects in its manufacture, design, testing, components and constituents, so that it would not safely serve its purpose, but would instead expose the patients, for which the VITAL TEMP PROBE was designed to benefit, to serious and/or deadly injuries and/or consequences because of the failure of defendants, and each of them, to properly guard and protect the end users of said VITAL TEMP PROBE, and all component parts thereof, from the defective design and/or manufacture of said product.

374. In addition, Vital Signs withheld from the marketplace crucial information regarding the performance limitations of their device making its use to measure temperature beyond its design capabilities not only foreseeable, but almost predictable.

375. NADINE and Plaintiff were not aware of said defects at any time prior to complications suffered by NADINE.

376. At all times herein mentioned, UCLA operated in the dual capacity of service provider and seller to the public of medical paraphernalia of almost every description.

377. In their dual capacity role, UCLA Defendants were not acting as "service providers" or "passive users" of the medical devices when they engaged in the surreptitious experimentation on NADINE with the Vital Signs Probe. Instead they stood in the shoes of "designers," "repackagers," "relabelers," "remanufacturers"(21 CFR 820.3(w)), and "distributors" of a new and heretofore unknown device,

namely Vital signs probe qua "Vital Signs atrio-esophageal fistula prevention tool." At least 14 patients were experimented on with this "new device," thus it was constructively placed into the stream of commerce by defendants without approval of the FDA for this use.

378. By reason of the foregoing, NADINE was required to employ the services of

**[Second Amended Complaint: Page 86; 1.CT .159]**

hospitals, physicians, surgeons, nurses and other professional services and was compelled to incur expenses for ambulance service, medicines, x-rays, and other medical supplies, services and sundries in an amount as yet unascertained. When said amounts are ascertained, Plaintiff will ask leave of the court to amend this complaint and allege said amounts.

379. That as a direct, legal and proximate result of the aforementioned acts of the defendants, and each of them, they have prevented NADINE from engaging in her usual occupation, thereby sustaining a loss of income both past and future, in an amount as of yet undeterminable. When said amounts are ascertained, Plaintiff will ask leave of the court to amend this complaint and allege said amounts.

**Eleventh Cause of Action**
**Survival Action - *CCP* §377.20**
**(As against all defendants)**

380. Plaintiff incorporates by reference the

allegations contained in paragraphs 1 through 379, and each and every party thereof with the same force and effect as though set out at length herein.

381. Plaintiff is the surviving spouse of, and lawful heir and successor in interest to the decedent, NADINE. All of NADINE's causes of action, therefore as previously pled and identified, survive and may be brought by Plaintiff pursuant to *California Code of Civil Procedure* §377.20.

382. Filed concurrently herewith is Plaintiff's declaration, pursuant to *California Code of Civil Procedure* §377.32, declaring that he is the successor in interest and succeeds to the decedent, NADINE F. SECAREA, interest in this action and/or proceeding.

WHEREFORE, Plaintiff, VALER V. SECAREA, JR., individually and in his capacity as successor in interest to the estate of the decedent, NADINE F. SECAREA, pray for judgment against the defendants, and each of them, as follows:

**[Damages omitted: Page 86-92; 1.CT .159-165]**

DATED: January 9, 2006
LAW OFFICES OF THOMAS E. ROCKETT, III

By /Original Signed/

THOMAS E. ROCKETT, III, ESQ.
Attorney For Plaintiff, VALER V. SECAREA, JR., individually and as Successor In Interest to NADINE F. SECAREA, decedent

**Second Amended Complaint Exhibit-A**

**20 December 1996 Letter from University of California Counsel Joanna M. Beam, re: medical experimentation regulation**

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**[Original: Page 1; 1.CT.167]**

December 20, 1996

DEANS OF MEDICAL SCHOOLS
VICE CHANCELLORS FOR RESEARCH

Re: California Application of FDA and NIH Exceptions to Informed Consent Requirements

Effective November 1, 1996, new FDA regulations permit research to be performed in limited circumstances when informed consent cannot be obtained from the patient or his/her legally authorized representative (61 Fed.Reg. 51498-51531) 21 C.F.R. pts. 50, 312 and 812 45 C.F.R. pt. 46), however, the new regulations do not preempt state or local requirements to protect human subjects. There is a conflict between the new federal regulations and California law, which requires that any human subject must give informed consent if they participate in a medical experiment. For the reasons set forth below, California law takes precedence over the new federal regulations.

Health & Safety Code section 24170, at seq.[83] (the "Protection of Human Subjects in Medical Experimentation Act", hereinafter referred to as the

---

[83]All further references shall be to the Health and Safety Code unless noted otherwise.

"Act")) sets forth the bill of rights for any human subject participating in an experimental study in California. Section 24172, subdivision (j) requires that the subject "[b]e given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision." In addition, section 24175, subdivision (a) provides:

"Except as otherwise provided in this section, no person shall be subjected to any medical experiment unless the informed consent of such person is obtained."

The phrase "medical experiment' ie defined broadly in section 24174 to mean:

**[Original: Page 2; 1.CT.168]**



> "(a) The severance or penetration or damaging of tissues of a human subject or the use of adrug or device as defined in Section 26009 or 26010, electromagnetic radiation, heat or cold, or a biological substance or organism, in or upon a human subject in the practice or research of medicine in a manner not reasonably

related to maintaining or improving the health of such subject or otherwise directly benefiting such subject."

"(b) The investigational use of a drug or device as provided in Sections 26678 and 26679."

"(c) Withholding medical treatment from a human subject for any purpose other than maintenance or improvement of the health of such Subject."

Based upon the foregoing, it does not appear that there are any applicable exceptions in California law to the requirement for prior consent. If the patient is unable to consent on his or her own behalf, the patient's legally authorized representative (a court appointed conservator or guardian, an attorney-in-fact - pursuant to a durable power of attorney, or parent) may consent on their behalf. If there is no legally authorized representative and the patient cannot consent, the patient may not be a human subject in a medical experiment in California.

The California Department of Health Service, and the California Office of the Attorney General are charged with enforcement of the provisions of the Act. Rumors have circulated that these departments have not and do not intend to enforce the provisions of the Act. University researchers should not rely on these rumors. The laws are in effect and the potential

liability for failing to conform to the provisions of the Act is substantial.

If a primary researcher willfully fails to obtain the informed consent of a human subject, and thereby exposes the subject to a known substantial risk of serious injury, either physical or psychological, the researcher will be guilty of a misdemeanor punishable by one year in jail and/or a fine of $10,000 (5 24176, subd. (c)). If there hasbeen no exposure to a substantial risk of serious injury, the researcher is liable in the amount of $1,000 if the failure to obtain consent was negligent, or up to $5,000 if the failure to obtain consent was willful (§ 24176, subds. (a) and (b)). Each experiment performed without the

**[Original: Page 3; 1.CT.169]**



consent of the human subject is a separate offense; thus, the penalties are cumulative (5 24176, subd. (e)).

For the reasons net forth above, it appears that there is conflict between California law and federal law. California law "prevails since it in more specific and provide, greater protection to human subjects. Therefore, until California law is amended or clarified, informed consent

must be obtained from any human subject or his/her legally authorized representative before the human subject may participate in a medical experiment.

If you have any questions, please do not hesitate to telephone me at (510) 987-9722.

/ Original Signed /
Joanna M. Beam
University Counsel

jms/sp

cc: M. Aarens
A. R. Amodeo
S. A. Arditti
D. G. Brown
W. R. Gurtner
C. L. Hopper, M.D.
J. King
J. F. Lundberg
G. Morrison
C. L. Nation, M.D.
R. N. Shelton
J. S. Stowsky
B. W. Yoder
Human Subjects Coordinators

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**18 September 2003 letter from Charles Swerdlow, M.D., to Michael Brodsky, M.D., describing the procedure agreed upon to treat Nadine**

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**[Original: Page 1; 3.CT.751; 3.CT.841, 4.CT.977]**

September 18, 2003

Michael Brodsky, M.D.
Bldg. 53 RR 81 UCI
101 City DRS
Orange, CA 92868

RE: Nadine Secarea

Dear Michael:

I had the pleasure of seeing Mrs. Secarea in consultation with her husband on 09/16/03. As you know, she is a 63-year-old woman, who has an approximately three-year history of repetitive paroxysmal atrial arrhythmias. Review of the tracing available to me demonstrated short runs of primary a trial arrhythmia, beginning with a n A PC. Some episodes remained a t least moderately organized, whereas other degenerated rapidly to atrial fibrillation. From the rhythm strips available to me, T-waves during tachycardia are positive in leads II, Ill, and $aV_F$, negative in $aV_L$, negative in $aV_R$, and probably slightly negative or isoelectric in $aV_F$. The T- waves are also quite narrow. Overall, this T-wave vector is suggestive of a posterior superior and probably atrial septal origin, possibly near the right superior pulmonary vein.

As you know, she has had trials of multiple

antiarrhythmic medications, including atenolol, which was not tolerated in significant doses, digoxin, diltiazem, which was ineffective, propafenone, which caused unacceptable nausea, and disopyramide, which has been initiated recently. Her reported echocardiograms have been normal or nearly normal. I am not aware of an evaluation for coronary disease, but she has no history of angina, syncope, or dyspnea.

PAST MEDICAL HISTORY:
Her past medical history is noncontributory. She indicates that she is allergic to both sulfa and Zoloft. She had a tonsillectomy at age eleven and hysterectomy 30 years ago.

REVIEW OF SYSTEMS:
Review of systems is positive for vertigo.

SOCIAL HISTORY:
She does not smoke or drink. She is married, and her husband is a consultant engineer.

PHYSICAL EXAMINATION:

| | |
|---|---|
| Vital Signs: | BP: 128/74. Pulse: 65. CVP: Less than 5 cm of water. |
| Chest: | Clear. |
| Cardiac: | Reveals no S3 or S4 gallop or murmurs. |
| Abdomen: | Benign. |
| Extremities: | No edema. Peripheral pulses were intact. |

**[Original: Page 2; 3.CT.752; 3.CT.842, 4.CT.978]**

DISCUSSION:

Mrs. Secarea came to me to discuss the risks and benefits of radiofrequency catheter ablation. I told her that overall, the success rate for an ablation in her case should be at least 80%, given the repetitive and apparently focal nature of her tachycardia.

I understand from our telephone conversation that you have additional evidence of organized atrial tachycardia on rhythm strips that were not available to me.

I also indicated to her that the complication rate for this type of ablation was in the range of 2% to 3%, including bleeding, vascular injury, venous thrombosis, and cardiac perforation. I told her that the risks of long-term serious complications were much smaller, probably in the range of about 1/2%, including such risks as clinically significant pulmonary vein stenosis, stroke, and myocardial infarction.

She a nd her h usband had m any detailed q uestions for me that t hey h ad g enerated through extensive review of material on the Internet. I explained to her that if, in fact, I identified a single focal source, I would target that site. If we were unable to identify a single focal source, the next best plan would be empirical pulmonary vein isolation.

I understand that Mrs. Secarea and her husband are going to seek multiple other opinions. I would be pleased to assist in her care in whatever she and you prefer.

Thank you for allowing me to participate in the care of this very pleasant patient.

Sincerely,

Charles D. Swerdlow, M.D.

CS/kk

**Declaration of defense expert,**
**Douglas Packer, M.D.,**
**in support of Dr. Swerdlow Summary Judgment**

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**[Original: Page 1; 3.CT.685]**

DECLARATION OF DOUGLAS L. PACKER, M.D. IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

I, Douglas L. Packer, M.D., declare as follows:

1. I am a physician duly licensed to practice medicine in the States of North Carolina and Minnesota and I have personal knowledge of the facts set forth herein. If called as a witness, I could and would competently testify thereto.

2. I graduated from the University of Utah College of Medicine in 1980. I completed an internship in Internal Medicine at Duke University in 1981. Thereafter, I completed my residency in Internal Medicine at Duke University in 1983. I am a board certified Diplomat for the American Board of Internal Medicine and have been since 1983. I have been a board certified Diplomat for the American Board of Internal Medicine in Cardiology since 1985. I am also certified by the American Board of Internal Medicine in Cardiac Electrophysiology through 2012. I am licensed in North Carolina and Minnesota. I belong to the North American Society of Pacing and Electrophysiology-Heart Rhythm Society. I am a Heart Rhythm Foundation Founder. I am also a Fellow of the American Heart Association Council on Clinical Cardiology since 2001. Additionally I am a Fellow for the American Heart Association Council on Basic Cardiovascular Sciences. I am also member of the American Heart Association and American Stroke Association. Further, I am a member of

the Cardiac Electrophysiology Society since 1985. Finally, I am a member and Fellow of the American College of Cardiology.

3. I was as an Associate and then Assistant Professor in Medicine at Duke University from 1985-1989. Thereafter, I was an Assistant and then Associate Professor of Medicine at the Mayo School of Medicine from 1993-1998. I am currently, and have been since 1998, a full Professor of Medicine at the Mayo School of Medicine. My practice centers on cardiac electrophysiology and research.

4. Based on my education, training, experience, I am familiar with the standard of care and practice as it applies presently and in 2003 through 2004, for care and ablative treatment of cardiac arrhythmias.

**[Original: Page 2; 3.CT.686]**

5. I have reviewed Nadine Secarea's medical records from UCLA Medical Center, Mission Hospital Regional Medical Center, Irvine Regional Hospital and Medical Center, Orange County Coroner and from her care with Michael Brodsky, M.D. My opinions herein are based upon my review of the above-mentioned materials, in addition to my education, training, and experience.

6. On September 16, 2003, the decedent, Nadine Secarea and her husband, Plaintiff, presented to Charles Swerdlow, M.D. for an interview and consultation regarding her repetitive paroxysmal atrial arrhythmias and the possibility of undergoing cardiac ablation therapy to treat those arrhythmias.

7. The records reveal clearly documented presence

of on going atrial fibrillation.

8. Also on September 16, 2003, by way of history, Ms. Secarea reported that she had been suffering from the arrhythmias for three years. She had been on multiple antiarrhythimc medications including atenolol, digoxin, diltiazem, propafenone. However, those medications proved to have intolerable side-effects or were ineffective.

9. During the September 16, 2003 visit, the various complications and risks of the ablation procedure were discussed with Ms. Secarea. Dr. Swerdlow reported that his success rate with patients, such as Ms. Secarea, was 80%. However, risks included in the procedure were bleeding, vascular injury, venous thrombosis and cardiac perforation. Dr. Swerdlow also discussed long term risks such as pulmonary vein stenosis, stroke and myocardial infarction. In his notes regarding the interview, Dr. Swerdlow noted that Ms. Secarea and her husband had done extensive research on the interne regarding the procedure and where quite knowledgeable on the subject.

10. After reviewing the test results of an ECG Stress Test, a Magnetic Resonance Imaging of the Heart and Great Vessels, and a Myocardial Spect Perfusion Study with both Resting and Treadmill tests, Dr. Swerdlow recommended Ms. Secarea undergo the procedure.

11. On August 10, 2004 Ms. Secarea signed a detailed informed consent for theprocedures. Specifically, the procedures she agreed to undergo included cardiac catheter ablation, cardiac catheterization, transesophageal echocardiogram and electrophysiology study.

She was informed of all the risks associated with each specific procedure. The risks included cardiac perforation including tamponade, transfusion and death. Listed under risks of the transesophageal echocardiogram was the risk of esophageal injury. It was further noted by Dr. David Cesario in the operative report, that Ms. Secare was cognizant of the risks and agreed to proceed with the procedure.

12. On August 11, 2004, Ms. Secarea underwent the cardiac ablation and related procedures. They were performed by Dr. Swerdlow and Dr. Cesario. No complications were noted during the procedures and Ms. Secarea was discharged home on August 12, 2004. Ms. Secarea was instructed to follow up with Dr. Swerdlow after one month following the procedure.

13. On September 12, 2004, Ms. Secarea passed away while under the care of Irvine Regional Hospital and Medical Center.

14. Based on the foregoing paragraphs and based upon my education, training and experience, and my review of the relevant records and the depositions, it is my professional opinion that Dr. Swerdlow complied with the standard of care at all times before, during, and after the cardiac catheter ablation and related procedures were performed.

15. Ms. Secarea was an appropriate candidate for ablation therapy. She had documented intermittent atrial fibrillation by way of ECG recordings and had undergone a trial of two different anti-arrhythmic medications without good results. Furthermore, her arrhythmia was

symptomatic, that is, she complained of dizziness and palpitations. As a result, Dr. Swerdlow's pre-operative testing and diagnosis of Ms. Secarea's eligibility for catheter ablation was within the standard of care.

16. The risks of Ms. Secarea's declining the ablation therapy would have included possible progression of her arrhythmia, possible formation of blood clots in the upper chamber of her heart and possible stroke. Further, she could have suffered from ongoing drug therapy and continued symptomatic arrhythmias.

**[Original: Page 4; 3.CT.688]**

17. Based on totality of the medical record, including the handwritten note of Dr. Swerdlow and the various consent forms executed by Ms. Secarea, it appears that the patient was advised of the risk of major complications including death.

18. The method Dr. Swerdlow employed during the ablation therapy, known as the wide area circumferential or Poppone technique, was well within the standard of care and is one that is used by the major centers treating patients with atrial fibrillation.

19. The power settings, temperature settings and burn times employed during the procedure by Dr. Swerdlow were appropriate and within the standard of care.

20. The use of esophageal temperature probe was reasonable and within the standard of care.

21. The post-operative care by Dr. Swerdlow was reasonable. At no time prior to her admission to Irvine Regional Hospital and Medical Center did Ms. Secarea or

her husband report any signs or symptoms to Dr. Swerdlow that were suggestive of an atrio-esophageal fistula.

22. Based on th- foregoing paragraphs and based upon my education, training and experience, and my review of the relevant records and the depositions, it is my professional opinion that to reasonable medical probability Ms. Secarea's demise was not attributable to any neglige on the part of Dr, Swerdlow.

1 declare under the penalty of perjury, under the laws of the State of California, that the foregoing is true and correct

Executed this 30 day of May, 2006, at Rochester Minnesota.

/ Original Signed /
Douglas L. Packer, M.D.
Declarant

**Declaration of defense expert,**
**Andrea Natale, M.D.,**
**in support of Regents, et. al., Summary Judgment**

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**[Original: Page 1; 2.CT.558]**

# DECLARATION OF ANDREA NATALE, M.D.IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT OR SUMMARY ADJUDICATION OF ISSUES

I, Andrea Natale, M.D., declare as follows:

1. I have personal knowledge of the following facts and, if sworn as a witness, I could and would competently testify to them.

## I. Qualifications

2. I am a physician, licensed to practice medicine in the State of Ohio. I am the Medical Director for the Center for Atrial Fibrillation, Director of the Electrophysiology Laboratories, Co- Section Head of Pacing and Electrophysiology, and Director of the Electrophysiology Fellowship Program at The Cleveland Clinic in the Department of Cardiovascular Medicine (aka the Heart Center). I am also a Professor of Medicine at Ohio State University. Incidentally, the Heart Center at The Cleveland Clinic has been ranked as the best cardiac care center in the nation for 11 consecutive years by U.S. News & World Report. I have been named one of the "Best Doctors in America" by U.S. News & World Report.

3. I am certified by the American Board of Internal Medicine in internal medicine, cardiology, and clinical cardiac electrophysiology. I am certified by the

Italian Board of Medicine and the Italian Board of Cardiology. I am a member of the North American Society of Pacing and Electrophysiology, the Ontario College of Physicians and Surgeons, the Italian Society of Cardiology, and the Italian College of Physicians.

4. I have been an invited lecturer at more than 100 cardiology symposiums and conferences worldwide. I am the author or co-author ofhundreds of published studies on pacing and electrophysiology. I serve as a reviewer on several editorial boards including PACE, the Official Journal of the North American Society of Pacing and Electrophysiology (NASPE), the Journal of American College of Cardiology, American Journal of Cardiology, Journal of Cardiovascular Electrophysiology, American Heart Journal, Circulation and Journal of Electrocardiology. I have served as a grader for abstracts presented at professional association meetings of the American Heart Association, American College of Cardiology and at NASPE.

**[Original: Page 2; 2.CT.559]**

5. I specialize in the treatment of abnormal heart rhythms. I am considered a leader in ablation therapy for the treatment of atrial fibrillation. I have pioneered some of the present catheter- based cures for atrial fibrillation. I was the first electrophysiologist in the nation to perform percutaneous epicardial radiofrequency ablation, which is a treatment for patients who fail conventional ablations. I have personally performed more than 2000 ablations.

6. A true and correct copy of my curriculum vitae,

which further details my education, training and experience, is attached as Exhibit A.

II. Review of Materials

7. I have reviewed the medical records of Nadine Secarea, including those from UCLA Medical Center, KALYANAM SHIVKUMAR, M.D., Irvine Regional Hospital & Medical Center, Cardiology Specialists of Orange County, Mission Hospital Regional Medical Center, Saddleback Memorial Hospital, Heart Center of Los Angeles, and the Orange County Coroner's Office. I have reviewed the Death Certificate and amended Death Certificate relating to Nadine Secarea. I have reviewed plaintiffs 2nd amended complaint. I have also reviewed the curriculum vitae of DAVID CESARIO, M.D. Based upon my review of these materials, as well as my education, training, and experience, I am familiar with the facts, allegations and issues in this case against DRS. SHIVKUMAR and CESARIO and THE REGENTS OF THE UNIVERSITY OF CALIFORNIA.

8. The medical records indicate that Nadine Secarea had a history of atrial fibrillation manifested by heart palpitations. Between October 2000 and January 2002 she underwent serial EKGs at Mission Regional Heart Center and the Heart Center of Los Angeles. She was also hospitalized in October 2000 and January 2001 for her cardiac condition.

9. In September 2003, Mrs. Secarea was admitted to Saddleback Memorial Medical Center through the emergency department with multiple near-syncopal

episodes and increasing palpitations. Her longstanding history of cardiac arrhythmia was documented, along with her positive family history of coronary artery disease. She had been seen by a number of physicians with episodic vertigo and palpitations, and had been tried on various antiarrhythmic medications with limited success.

**[Original: Page 3; 2.CT.560]**

10. On September 18, 2003, Mrs. Secarea presented to cardiologist and electrophysiologist CHARLES SWERDLOW, M.D. to discuss the risks and benefits of radiofrequency catheter ablation. DR. SWERDLOW documented a detailed discussion he had with the patient regarding the risks of the procedure, including the risks of esophageal injury and death. The patient planned to seek multiple other opinions. On December 1, 2003, she emailed DR. SWERDLOW stating that she wanted the catheter ablation. She indicated that she would prefer to have the ablation performed by DR. SWERDLOW and DR. SHIVKUMAR if possible.

12. On December 22, 2003, the patient was seen in consultation by cardiologist and electrophysiologist KALYANAM SHIVKUMAR, M.D. DR. SHIVKUMAR took a history, performed an evaluation, and discussed with the patient her options for therapy. These options included a catheter ablation for atrial fibrillation. DR. SHIVKUMAR obtained additional diagnostic studies (e.g., an EKG, a cardiac MRI, a treadmill stress test) to further evaluate the patient.

13. On August 10, 2004, the patient signed a

number of informed consent forms at UCLA Medical Center. These forms provided her with detailed information about the procedures she was scheduled to undergo, including the cardiac catheter ablation, cardiac catheterization, transesophageal echocardiogram and electrophysiology study. Each of the consent forms informed the patient of the procedures' risks. The consent forms for the cardiac catheter ablation and the cardiac catheterization expressly informed Mrs. Secarea, "You may die from the procedure." The patient also signed a consent form authorizing DR. SWERDLOW or DR. SHIVKUMAR and the associates and assistants of his choice to perform the procedures.

14. On August 11, 2004, the patient underwent a catheter ablation for atrial fibrillation at UCLA Medical Center. The operative report indicates that a detailed and written informed consent had been obtained from the patient, who was aware of the risks -- including cardiac perforation and death. Left atrial ablative lesions were created with linear lesions encircling all pulmonary veins, left atrial roof and left inferior pulmonary vein to mitral annulus. DR. SWERDLOW performed the ablation and electrophysiology fellow DAVID CESARIO, M.D. assisted. No intra-procedure complications were apparent. On August 12, 2004, the patient was discharged home with instructions to follow up with DR. SWERDLOW in 1 month.

**[Original: Page 4; 2.CT.561]**

15. Approximately 31/2 weeks later, on

September 6, 2004, Mrs. Secarea presented to the emergency department at Irvine Regional Hospital & Medical Center with an acute onset of left- sided weakness and an episode of altered level of consciousness. She was also septic and had a fever. She was assessed as having had a probable transient ischemic attack and was admitted to the hospital. On September 7, 2004, she became unresponsive and was transferred to the ICU. On September 8, 2004, a CT scan of the head revealed a large middle cerebral artery infarct with notable midline shift. The patient remained comatose and unresponsive. An EEG revealed findings consistent with clinical brain death. A chest CT scan to rule out an atrio-esophageal fistula was inconclusive. On September 9, 2004, the patient was in consultation by a pulmonologist who believed her clinical picture was highly suggestive of an atrio-esophageal fistula complication of the ablation therapy, but confessed that he had been completely unfamiliar with that complication until reviewing the medical literature. A videotape esophagram to evaluate for atrio-esophageal fistula was normal. On September 11, 2004, a brain flow study confirmed the absence of any brain activity. On September 12, 2004, all therapy was discontinued and the patient was pronounced. On September 14, 2004, an autopsy was performed at Irvine Regional Hospital & Medical Center. A 0.4 cm perforation was found in the mid-esophagus extending into the adjacent left atrium. This was identified as an atrio-esophageal fistula.

16. On September 15, 2004, DR. SWERDLOW authored the following addendum to the August 11, 2004 cardiac ablation operative report:

Approximately one month post procedure, in the interval between Dr. Cesario's dictation and today, the patient died of a stroke that may have been caused by an atrio-esophageal fistula. With regard to this concern, I note that all ablations on the posterior wall or roof of the left atrium were performed with a power setting of 50 watts and temperature setting of 50 degrees. In addition to the role of intracardiac echo mentioned in Dr. Cesario's dictation, it was used to monitor for showers of microbubbles during the procedure, and none were observed.

After his wife's stroke, the patient's husband questioned whether I was present for this procedure and questioned Dr. Cesario's role. For this reason, I am

**[Original: Page 5; 2.CT.562]**

taking the unusual step of stating explicitly that I was the attending physician for this case. I performed the ablation as principal operator, I was present for the entire duration of the case, and Dr. Cesario functioned in the role of fellow-assistant.

17. On September 20, 2004, the Orange County Coroner's Office determined that further investigation was needed to determine the cause of death. On December 20, 2004, the immediate cause of death was identified as anoxic/ischemic encephalopathy. Conditions leading to the

cause of death included systemic air/clot embolism, esophago-left atrial fistula, and complication of radiofrequency catheter ablative therapy for atrial fibrillation, clinical.

III. Opinions

18. In the 2nd amended complaint, plaintiff alleges medical malpractice and lack of informed consent by THE REGENTS and DRS. SHIVKUMAR and CESARIO. Plaintiff contends that the ablation and the esophageal temperature probe used during the ablation were experimental. He contends that his wife was not informed that an atrio-esophageal fistula was a risk of the ablation. He contends that the ablation should have been performed by DRS. SWERDLOW and SHIVKUMAR, not DRS. SWERDLOW and CESARIO. Finally, he contends that these departures from the standard of care caused his wife's death.

Standard of Care

19. Based upon my education, training, and experience in the field of cardiovascular diseases generally and in the performance of catheter ablations specifically, I am familiar with the standard of care applicable to THE REGENTS and DRS. SHIVKUMAR and CESARIO. I am of the professional opinion that all of the care and treatment rendered by THE REGENTS and its agents and employees, including DRS. SHIVKUMAR and CESARIO, to Nadine Secarea before, during and after the August 11, 2004 ablation met the standard of care in this case.

20. Mrs. Secarea had chronic and symptomatic atrial fibrillation. Atrial fibrillation is an abnormal heart rhythm (or arrhythmia) originating in the top chambers of the heart (or atria). Instead of an impulse traveling in an orderly fashion through the heart, many impulses begin and spread through the atria, causing a rapid and disorganized heartbeat (or flutter). Chronic atrial fibrillation is associated with heart failure, blood clots, a five to sevenfold increase in stroke, and increased

**[Original: Page 6; 2.CT.563]**

mortality from heart disease. In fact, atrial fibrillation is the leading cause of stroke in this country.

21. Mrs. Secarea was an appropriate candidate for catheter ablation in August 2004. Her atrial fibrillation was refractory to antiarrhythmic medications and became progressively more frequent and intense. Catheter ablation is a procedure performed to prevent abnormal electrical impulses. During an ablation, the electrophysiologist maps the heart's electrical activity to pinpoint the precise area at which the abnormal impulse starts. The tip of the ablation catheter is then positioned at the site and a radiofrequency current is applied. This creates a tiny scar in the heart which blocks the abnormal electrical activity and restores a normal heart rhythm. The decision to perform a catheter ablation on Mrs. Secarea was consistent with the standard of care.

22. The August 2004 catheter ablation was performed well within the standard of care. The medical records describe a text-book ablation. Every aspect of the

procedure -- including all of the power settings, temperature settings and burn times -- was appropriate. The ablation was in no way, shape or form experimental.

23. Mrs. Secarea signed consent forms for the catheter ablation, cardiac catheterization, transesophageal echocardiogram and electrophysiology study. These forms were detailed and satisfied the standard of care. Each of these forms described the particular procedure in detail, along with its risks and possible complications. Among a number of other risks, Mrs. Secarea was informed of the risks of esophageal injury, cardiac perforation and death. In addition, plaintiff's 2nd amended complaint expressly indicates that Mrs. Secarea and her doctors discussed the risks and possible complications of these procedures. The catheter ablation performed on Mrs. Secarea was the same ablation procedure to which she consented.

24. An atrio-esophageal fistula -- i.e., the formation of a hole between the atrium and the esophagus -- is a rare and usually fatal complication of catheter ablation for atrial fibrillation. The mechanism of injury is believed to be a disruption of the muscle of the atrium that slowly creates a passage through the esophagus. Although some in the electrophysiology community believe that the incidence of this complication is as high as 1 percent, only about 18 atrio-esophageal fistulas have been reported worldwide out of approximately 20,000 to 30,000 catheter ablations for atrial fibrillation -- suggesting that the risk of this complication is far less than 1 percent.

**[Original: Page 7; 2.CT.564]**

25. There was nothing in Mrs. Secarea's medical history or about her cardiac condition that made the risk of atrio-esophageal fistula or death more likely. Likewise, there was nothing in the way the August 2004 catheter ablation was performed that made the risk of atrio-esophageal fistula or death more likely. That an atrio-esophageal fistula occurred in this case does not suggest a departure from the standard of care. An atrio-esophageal fistula occurred here even though the ablation was performed properly. Furthermore, these defendants did not negligently fail to diagnose or treat the atrio-esophageal fistula once it occurred.

26. There is no standard approach to avoiding an atrio-esophageal fistula. Even today, there is no sure way to prevent its occurrence. An esophageal temperature probe can be a useful tool for structural visualization, as well as for analysis of tissue temperatures during ablation procedures. The use of an esophageal temperature probe during the August 2004 ablation was consistent with the standard of care. It was then, and still is now, an appropriate means of monitoring temperature in the esophagus. The risk of an atrio-esophageal fistula was not increased by the use of an esophageal temperature probe during the ablation.

27. The use of an esophageal temperature probe was not considered experimental or investigational in August 2004. Additionally, the standard of care did not require that the defendants inform Mrs. Secarea that an esophageal temperature probe would be used during the August 2004 procedure.

28. Worth mentioning, esophageal temperature

probes are used at the Heart Center at The Cleveland Clinic during all catheter ablations and, as indicated earlier, the Heart Center has been voted the best cardiac care center in the country for the past 11 years.

29. Another way to try to reduce the risk of atrio-esophageal fistula is to use intracardiac echocardiography during catheter ablation. Intracardiac echocardiography can, among other things, help monitor the position of the esophagus during the ablation. Here, the defendants appropriately used intracardiac echocardiography during the August 2004 ablation.

30. Death is a risk of catheter ablation. The standard of care required that Mrs. Secarea be informed of the risk of death, and the medical records indicate that she was informed of and accepted this risk. That she accepted the risk of death indicates that she accepted the risk of an atrio-

**[Original: Page 8; 2.CT.565]**

esophageal fistula-related death. The standard of care did not require that Mrs. Secarea be informed of each and every way she could die. Knowing that death could occur, rather than knowing how it could occur, is the important factor for a reasonable patient to decide whether to undergo or decline a catheter ablation. The standard of care did not require the specific disclosure of the risk of atrioesophageal fistula or death from an atrio-esophageal fistula. Also, that Mrs. Secarea died following the catheter ablation does not suggest a departure from the standard of care. Indeed, her death occurred in this case even though the ablation was

performed properly.

31. There is nothing to suggest that the performance of the August 2004 catheter ablation was motivated by any academic or publishing interest of these defendants. On the contrary, the ablation was medically indicated and Mrs. Secarea was an appropriate candidate for the procedure. She was consented for esophageal injury, cardiac perforation and death. The decision to perform the ablation and the decision to utilize an esophageal temperature probe were consistent with the standard of care. Neither the ablation nor the esophageal temperature probe was experimental.

Causation

32. Based upon my education, training, and experience in the field of cardiovascular diseases generally and in the performance of catheter ablations specifically, I am familiar with the issues of causation in this case. In my professional opinion, there is no reasonable medical probability that THE REGENTS or its agents or employees, including DRS. SHIVKUMAR and CESARIO, were a substantial factor in causing any harm to Nadine Secarea, including her death.

33. To a reasonable medical probability, there is no causal relationship between the alleged failure to inform of the risk of atrio-esophageal fistula and the death of Mrs. Secarea. It cannot be stated to a reasonable medical probability that a reasonable patient with chronic and symptomatic atrial fibrillation would have declined the catheter ablation if the specific risk of atrioesophageal

fistula been disclosed. In my professional opinion, a reasonable patient with Mrs. Secarea's condition could not have declined the catheter ablation even if this specific risk had been disclosed. This is because the risks of heart failure, stroke and death increased significantly without a catheter ablation. Given the gravity of these risks, any reasonable person would have made the same decision as Mrs. Secarea made -- i.e., to undergo the ablation.

**[Original: Page 9; 2.CT.566]**

34. The patient signed a consent form expressly authorizing DR. SWERDLOW or SHIVKUMAR "and associates and a. sistants of his choice" to perform the catheter ablation. The standard of care allowed the defends rits to assume that the patient read the consent form before signing it. DR. CESARIO's curriculum vitae demonstrates that he is a very well-credentialed and experienced cardiologist and electrophysiologist. There is no suggestion that DR. GESARIO was anything other than qualified to assist DR. SWERDLOW during the August 11, 2004 catheter ablation. DR. CESARIO had graduated from medical school 8 years prior to the ablation. He had completed an internship and cardiology residency. He was a fellow in electrophysiolttgy at the time of the ablation, and fellows routinely assist in the performance of catheter ablations.

35. There is nothing in the aedical records to suggest that DR. SHIVKUMAR promised the patient that he would personally participate in the August 11, 2004 catheter ablation. Moreover, there is no reasonable medical

probabi ity that the patient's outcome would have been different even if DR. SHIVKUMAR had participated instead of DR. CESARIO. Conversely, there is a reasonable medical probability that the atrio-esophageal fistula would still have occurred and the patient would still have died if DR. SHIVKUMAR, and not DR. CESARIO, had assisted DR. SWEFLDLOW. The catheter ablation in this case was performed well within the standard of care. An atne-esophageal fistula occurred, and Mrs. Secarta died, even though the ablation was performed properly. Mrs. Secarea died from a rare complication of the ablation and not as the result of negligence.

Conclusion

36. THE REGENTS and its agents and employees, including DRS. SHIVKUMAR and CESARIO, met the standard of care in his case and, to a reasonable medical probability caused no harm to Nadine Secarea.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 24th day of May 2006, at Cleveland, Ohio.

/Original Signed/
Andrea Natale, M.D., Declarant

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**Declaration of Plaintiff**
**Valer V. Secarea, Jr.**
**in opposition to Summary Judgments**

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**[Original: Page 1; 3.CT.794, 4.CT.960]**

DECLARATION OF VALER V. SECAREA

I, Valer V. Secarea, Jr, declare as follows:

1. I am a personal witness to all that I describe. I attended every office visit of every doctor Nadine consulted with respect to the cardiac catheter ablation which is at issue in this case. I accompanied Nadine to every test that was performed on her in preparation for the ablation procedure. I also accompanied Nadine to the ablation procedure itself, reviewing all documents and consents signed by her. Nadine. I reviewed all material matters involving the cardiac catheter ablation procedure with her physicians in order to ensure that some important detail would not be overlooked.. I am also an aerospace engineer and I have applied my knowledge of basic engineering principles to analyze and evaluate the esophageal temperature monitoring experiment that Nadine was subjected to.

2. After suffering since about the year 2000 with atrial tachycardia, Nadine and I investigated the possibility of having an elective cardiac catheter ablation performed to cure her atrial tachycardia. Nadine had experienced episodes of atrial tachycardia which had required annual visits to the emergency room since her first episode in 2000, and admission for observation every year since 2001. Finally, while hospitalized in August 2003, Norpace (disopyramide) restored her normal ("sinus") heart rhythm and according to my observations of her activity, she was

tolerating it well.

3. Nadine's cardiologist Dr. Michael Brodsky explained to us that Nadine's condition was best described as atrial tachycardia rather than atrial fibrillation. He also explained that the kind of clotting and stroke that might accompany true atrial fibrillation was an unlikely occurrence for Nadine's condition.

4. In 2003, while Nadine was hospitalized, Dr. Michael Moran diagnosed Nadine with syndrome-x or metabolic syndrome, and suggested that this might be the underlying cause of her atrial tachycardia. Dr. Moran suggested a diet which he claimed might help Nadine's total circumstances.

5. However, after three years of "annual hospitalizations," Nadine and I decided to research the benefits and risks of the ablative therapy and have it performed electively, at a time,

**[Original: Page 2; 3.CT.795, 4.CT.961]**

place and by practitioners of her choosing.

6. We studied ablative therapy on the Internet. We reviewed publicly available information and attempted to become knowledgeable enough to ask meaningful questions regarding Nadine's prospects for ablative therapy. However, we were not so knowledgeable that we could not be misled by incomplete, ambiguous or fragmented information.

7. After researching physicians and institutions, the Nadine and I met with Dr. Charles Swerdlow at his offices on September 16, 2003. Dr. Swerdlow discussed some of the risks and benefits of ablative therapy, and, per a letter,

dated September 18, 2003 (Exhibit 1), from Dr. Swerdlow to Dr. Brodsky, Nadine's cardiologist, detailed a very conservative approach to curing Nadine's arrhythmia, namely ablating sources of electrical foci, and if that were not sufficient, only then to perform an Empirical Pulmonary Vein Isolation procedure. According to this record, on page 2, it was this approach to treatment that Nadine consented to. Dr. Swerdlow explained the Empirical Pulmonary Vein Isolation Procedure by drawing rings around each of the two orifices of an image of the inside of a left atrium depicted on his MacIntosh computer screen According to Dr. Swerdlow, there were no other "lines" ablated in this particular ablation scheme. This approach appealed to Nadine since she stated that she didn't want any more cardiac tissue destroyed (ablated) within her heart than was absolutely necessary to cure her arrhythmia.

8. Dr. Swerdlow's discussed many, but not all, of the risks and benefits of cardiac ablative therapy. These included bleeding, vascular injury, venous thrombosis, cardiac perforation, pulmonary vein stenosis, stroke, and myocardial infarction. It is noteworthy, however, that Nadine's demise did not result from any of the complications disclosed to her. It was a result of one not disclosed, the atrio-esophageal fistula complication that caused the chain of events leading to her untimely death.

9. At an office visit with Dr. Brodsky, he showed us Dr. Swerdlow's 18 September 2003 letter. We asked Dr. Brodsky if the recommended procedure was the conservative approach that Nadine desired. Dr. Brodsky opined that the approach recommended by Dr. Swerdlow would meet Nadine's needs in this regard.

10. Dr. Swerdlow had informed us that ablation procedures are performed by a team

**[Original: Page 3; 3.CT.796; 4.CT.962]**

of two physicians. To this end, Nadine engaged in a significant dialog with Dr. Swerdlow over this choice, most of it recorded in her e-mail communications with him (Exhibit 3).

11. The record of these e-mails shows that Dr. Swerdlow and Nadine discussed options to have the ablative therapy performed at either UCLA Medical Center or Cedars Sinai Medical Center. Among the choices Dr. Swerdlow presented Nadine was that her ablative therapy could be performed by himself and Dr. Shivkumar at UCLA But, if the procedure were performed at Cedars Sinai, it could be done either by Dr. Swerdlow and a senior electrophysiologist fellow or by Dr. Swerdlow and his partner Dr. Eli Gang.

12. In a December 1, 2003 e-mail to Dr. Swerdlow, Nadine conditioned her consent to ablative therapy on its being personally performed by Dr. Swerdlow and Dr. Shivkumar, if the procedure was done at UCLA Medical Center, and by Dr. Swerdlow and Dr. Eli Gang, if the procedure were done at Cedars Sinai Medical Center. Conspicuously, Nadine declined to have her ablative therapy performed by Dr. Swerdlow and an electrophysiologist fellow.

13. In the e-mail correspondence between Nadine and Dr. Swerdlow, see especially, the 18 September 2003 e-mail to Dr. Swerdlow beginning on circled page 6 of

Exhibit 3 and the 1 December 2003 e-mail beginning on circled page 16 of Exhibit 4. There Nadine specifically stipulates that if her procedure were done at UCLA, then Drs. Swerdlow and Shivkumar were to personally perform it.

14. After communicating these choices to Dr. Swerdlow, Nadine and I visited with Dr. Shivkumar at his UCLA office. Dr. Shivkumar's December 22, 2003 report (Exhibit 2) on Nadine's visit is in accord with Dr. Swerdlow's September 18, 2003 letter to Dr. Brodsky.

15. Dr. Swerdlow and Dr. Shivkumar accepted Nadine as a patient as evidenced by her e-mail communications with both physicians (Exhibits 3 and 4).

16. Dr. Shivkumar coordinated Nadine's ablation candidacy testing which took place on 29 July 2004. Nadine's many e-mail communications with Dr. Shivkumar (Exhibit 4) make this arrangement clear.

17. On 29 July 2004, I accompanied Nadine to UCLA Medical Center where she underwent an ECG Stress Test, a Magnetic Resonance Imaging of the heart and great vessels,

**[Original: Page 4; 3.CT.797, 4.CT.963]**

and a Myocardial SPECT (Single Photon Emission Computed Tomography) perfusion study with both resting and treadmill tests.

18. Nadine and I met briefly with Dr. Shivkumar late in the afternoon of 29 July 2004. At that time Dr. Shivkumar reviewed Nadine's test results with us and assured us that Nadine was a good candidate for ablative

therapy. Then, later that evening, Nadine directed an e-mail to Dr. Shivkumar regarding the specific inquiries she had about her surgery.

19. On August 10, 2004, Dr. Shivkumar, Nadine and I met to discuss last minute preparations and to sign the detailed informed consents for her ablation therapy. It was my and Nadine's understanding that the ablative therapy that Nadine was consenting to was that which was described in Dr. Swerdlow's September 18, 2003 letter to Dr. Brodsky, to wit, ablation of electrical foci, with an Empirical Pulmonary Vein Isolation procedure, if needed.

20. Once again, Nadine was informed of the risks associated with cardiac catheter ablation, except one, the atrio-esophageal fistula, the very complication which took her life.

21. Besides the Empirical Pulmonary Vein Isolation, the procedures Nadine agreed to undergo included cardiac catherization, transesophageal echocardiogram and electrophysiology study. Nadine was also informed of the risks associated with these procedures. Although esophageal injury is included under the risks of the transesophageal echocardiagram (TEE), Nadine was not injured during the course of the TEE procedure, so this complication is moot to Nadine's ablation therapy experience.

22. Of particular note in the set of consents that Nadine and Dr. Shivkumar signed (Exhibit 6) was the Consent to Operation and Other Procedures (Exhibit 6-1). On the first line of this form is found the names of Drs. Shivkumar and Swerdlow in comma-separated conjunctive list form.

23. During our long discussion with Dr. Shivkumar the evening of 10 August 2004, when Nadine and Dr. Shivkumar signed the "Consent to Surgery and Other Procedures," she insisted that Dr.Shivkumar fill in both his name and that of Dr. Swerdlow as her surgeons. Nadine specifically inquired who the other "physicians" and "associates" mentioned on this form might be. Dr. Shivkumar explained that these were the anesthesiologist, nurses, and other

**[Original: Page 5; 3.CT.798, 4.CT.964]**

"support" personnel who were not directly involved in performing the ablation procedure as he and Dr. Swerdlow would be. Since I was present at this meeting, I can attest to the fact that Dr. Shivkumar assured Nadine (and me) that he and Dr. Swerdlow would be personally performing Nadine's ablation procedure.

24. Nadine and I were led to understand that the entry of the names of Drs Shivkumar and Swerdlow as named surgeons on the Consent to Surgery and Other Procedures form merely finalized what had already become a firmly established and well-documented condition to treatment as evidenced by Nadine's many e-mail communications with Drs. Swerdlow and Shivkumar (Exhibits 3 and 4). That Nadine and I had every reasonable expectation that Dr. Shivkumar and Dr. Swerdlow would personally perform her ablative therapy cannot be denied. Every communication between Nadine and Drs. Swerdlow and Shivkumar attests to this understanding.

25. In addition to the significant communications

supporting Nadine's expectation that Drs. Shivkumar and Swerdlow would personally perform her Empirical Pulmonary Vein Isolation procedure, Dr. Shivkumar had designated himself as Nadine's attending physician in a UCLA Medical Center Doctors Orders form, dated August 10, 2004 (Exhibit 13).

26. During our discussion with Dr. Shivkumar, Nadine and I made several inquiries about the ablation procedure, its aftermath and after-care. But, as I read the "consents," authored by UCLA Medical Center, I noticed that patients were advised that they assume the risks of this procedure. So together, Nadine and I attempted to be sure that Nadine understood all of the dangers she might be subjected to.

27. One of the warnings, number 12, on the "Informed Consent Information - Cardiac Catheter Ablation," states that the death is a possible complication of this procedure. I pointed out to Dr. Shivkumar that I thought that this warning was so ambiguous and vague as to be almost meaningless in deciding whether or not to have this procedure performed. I asked Dr. Shivkumar if he might qualify this warning by telling Nadine and me what kinds of conditions might result in the death of a patient undergoing a catheter ablation. He replied with a list of infirmities which he believed could compromise a patient's chances of having a safe, if not

**[Original: Page 6; 3.CT.799, 4.CT.965]**

successful ablation. I asked him if Nadine was at risk for any of these problems. He answered "no."

28. It is noteworthy that the one complication that Nadine was not informed of was the almost always fatal atrio-esophageal fistula complication. Although Drs. Swerdlow and Shivkumar had informed me just before and after Nadine's death that they knew of this complication since at least April 2004, there is no mention of it in any of the material provided to Nadine in either the informed "consents" (Exhibit 6) that she signed or in any of the literature about the catheter ablation procedure that she received from UCLA (Exhibit 5), Dr. Swerdlow or Dr. Shivkumar. Nor did Nadine of I happen upon it in the research we did.

29. If Nadine had known about the atrio-esopageal fistula complication, she would not have consented to the ablation procedure until such time as both she and I had studied it and come to some resolution, with her doctors, as to whether and how it might be completely avoided.

30. Another document that I recall Nadine signing was a "Terms and Conditions of Service Confidentiality of Information - UCLA" – or words to that effect (hereinafter Terms and Conditions Agreement). This document also became a point of some discussion. The document contained a "Teaching Hospital" clause which said, in essence, that medical personnel-in-training might be "observers" of the undersigned patient's care. When I read this clause in the Terms and Conditions Agreement that Nadine signed, my comment was: "its nice to know that they [medical personnel-in-training] can look, but they can't touch."

31. On 11 August 2004, around 9:00 a.m. Nadine was wheeled into the Electrophysiology Lab on a gurney. While I waited for Nadine to be "cured," I roamed the

hallways of UCLA Medical Center dividing my time between the surgical lounge and standing just outside the door of the EP Lab where Nadine's procedure was taking place, I happened to be in the hallway outside the Lab at around 3:30 p.m., when I saw Dr. Shivkumar round a corner and walk down the hallway toward me. I was surprised to see him there. He was in street clothes rather than in the "scrubbs" that I had sen other EP Lab personnel wearing that morning. Dr. Shivkumar didn't speak a word to me. He merely half-smiled and entered the Lab.

**[Original: Page 7; 3.CT.800, 4.CT.966]**

32. What I didn't know at this time was that Dr. Shivkumar had left Nadine at the start of her ablation procedure and had not personally performed the procedure with Dr. Swerdlow as he had promised he would, just the night before. I would not be informed of this fact until just before and after Nadine's death. 33. Later that evening, around 8:30 p.m., Dr. Shivkumar stopped in to see Nadine in her hospital room at UCLA Medical Center. After a cursory examination, he told us that the ablation procedure had been a complete success and that Nadine's prognosis was excellent.

34. Nadine was released from UCLA Medical Center on 12 August 2004. We were informed that she would need to take blood thinners, first Heparin for several weeks, then Coumadin for several months. Dr. Swerdlow was responsible for Nadine's post-surgical care and for her Coumadin management. Dr. Swerdlow's office provided

Nadine with prescriptions for Coumadin and orders for INR (International Normalized Ratio) blood tests which would be used to monitor Nadine's Coumadin effectiveness.

35. I accompanied Nadine to Mission Hospital for each of her INR blood tests. Finally, Nadine's INR began to climb rapidly toward 2.5 and we were instructed by Dr. Swerdlow's nurse, Kerry, to discontinue the Heparin. Now all we need to do was wait for Nadine to heal – or so we thought.

36. We had been led to believe By Drs. Swerdlow and Shivkumar, that our only and overriding concern was that Nadine's blood thinners/anti-clotting agents be meticulously monitored and maintained at a therapeutic level while Nadine's ablated heart was healing. So far as we were aware, preventing blood clotting while Nadine's ablated heart tissue was repairing itself was the only obstacle between her current condition and her complete recovery.

37. But, because the atrio-esophageal fistula complication was never disclosed to Nadine, we were totally unprepared to seek the immediate medical intervention she would desperately need after symptoms finally began to appear. Indeed, Drs. Swerdlow and Shivkumar remained silent about this complication until it was far too late to save Nadine's life.

38. Even though it was a holiday, I went to work 6 September. I had a lot to catch up on since I was taking whatever time was necessary to attend to Nadine's needs. While on my way

**[Original: Page 8; 3.CT.801, 4.CT.967]**

home, Nadine called me to tell me that she began having vision disturbances and tingling in her extremities. When I came through our front door, Nadine was sobbing and was very shaken.

39. After Nadine described her symptoms in more detail, we called Dr. Swerdlow's office. His answering service told us that they would forward our concerns to him. While we waited to hear from Dr. Swerdlow, we prepared our dinner.

40. We had just "set the table," when Dr. Swerdlow finally returned our call. Nadine and I picked up separate telephones receivers so that we could both participate in this conversation. I listened while Nadine described her symptoms to Dr. Swerdlow. Nadine explained that she had been experiencing visual disturbances, like looking at her hands and having a sense that she was seeing them through a telescope. She described feeling tingling and numbness in her hands and arms. I then asked Dr. Swerdlow what Nadine's symptoms might mean and we should do. Dr. Swedlow seemed indecisive. He suggested that we could go to the emergency room, and have a CT Scan done on Nadine. However, he cautioned, the CT Scan might show nothing and we would have made a trip to the emergency room for nothing. So he advised that we "wait and see."

41. Nadine and I had just begun to eat our now very late diner when Nadine looked across the table at me and said "I'm getting that funny feeling again" (referring to the visual symptoms she had just described to Dr. Swerdlow). She no sooner said "again," when she collapsed. I called 911 and reported that Nadine needed emergency assistance. The 911 operator took my name and address

and dispatched an ambulance.

42. About the time EMS personnel arrived, Nadine had recovered. I very quickly told her what had happened, then ran for the front door to admit the EMS personnel. Nadine was transported to the Emergency room of Irvine Regional Hospital and Medical Center (Irvine Regional). There we waited about a half hour before Nadine was first seen by a physician.

43. Only minutes after we arrived at the Irvine Regional Emergency Room, I called Dr. Swerdlow to report on Nadine's condition. However, I could only leave a message as to what had transpired and await his return call. Dr. Swerdlow did not return my call. Nadine was admitted to Irvine Regional and I inquired as to what had occurred. I was informed that Nadine

**[Original: Page 9; 3.CT.802, 4.CT.968]**

had experienced a TIA (Transient Ischemic Attack).

44. The next day I called Dr. Swerdlow's office again to inform him of Nadine's condition, but was told that Dr. Swerdlow was unavailable. So, I left a message. Sometime after 4:00 p.m. I witnessed Nadine experience another "TIA." I ran from Nadine's room to summon assistance, but no one was at the nurses station. After some frantic searching, I located Nadine's nurses, on a "break." I explained to them what had happened and we all rushed for Nadine's room. At some point one of the nurses called a "code blue" over the hospital's public address system. After stabilizing Nadine, she was taken to the ICU.

45. While I was waiting in the ICU with Nadine,

who was now unconscious, my cell phone rang. It was Dr. Swerdlow. I explained te situation to him, as best I could from the scant information I had at that time. Dr. Swerdlow told me that he wold contact Nadine's Irvine Regional physicians to appraise him of Nadine's condition. At that time I asked Dr. Swerdlow to transfer Nadine to either UCLA or Cedars Sinai. He agreed to see to the arrangements.

46. During that week, from 8 September to 10 September, I leaned from Dr. Swerdlow about the atrio-esophageal fistula complication, about Dr. Cesario's role in Nadine's ablation procedure and about the medical research experiment that Nadine had been surreptitiously subjected to.

47. Dr. Swerdlow first disclosed the atrio-esphageal fistula complication to me. Next he explained how he and Dr. Shivkumar had theorized that an anaesthesiologist's temperature probe could be used to monitor esophageal temperature during ablation procedures to protect against the atrio-esophageal fistula complication. I inquire how he and Dr. Shivkmar had determined that this device could be used for a purpose for which it was neither designed or intended. Dr. Swerdlow had no answer.

48. So far as I was made aware, Dr. Swerdlow remained in contact with Irvine Regional Physicians and I discussed Nadine's condition with Dr. Swerdlow every day through Friday. Each day, I asked about transferring Nadine from Irvine Regional, but Dr. Swerdlow explained that Nadine could not be moved until she "stabilized."

49. On Thursday, Dr. Swedlow informed me that Cedars Sinai Medical Center would

be "proud" to accept the transfer of Nadine to their facility to continue her care, once she stabilized. I then inquired what would be done once Nadine was transferred to Cedars Sinai. Dr. Swedlow explained that a metallic tube would be placed in her esophagus to seal off any fistula she might have. I later learned that the "tube" Dr. Swedlow was referring to was an expandable metal stent, used to seal esophageal injuries.

50. On Friday I was informed by Irvine Regional medical personnel that they feared Nadine may be brain dead. I communicated this news to Dr. Swerdlow.

51. It was at that time that Swedlow disclosed to me that an understudy of his and Dr. Shivkumar, one Dr. David Cesario, had "done the burn" [as Dr. Swerdlow described the application of RF energy] on Nadine "under his [Dr. Swerdlow's] "supervision," and that Dr. Shivkumar took no part in Nadine's ablation procedure. He had evidently left the EP Lab just as soon as Nadine was under anesthesia.

52. When I demanded to know, referring to Dr. Cesario, and in words almost identical to these, "Who is this guy?" "Why was he operating on Nadine?" "Nadine and I never interviewed him, we know nothing about him, and there was never an understanding that anyone but you [Dr. Swerdlow] and Dr. Shivkumar would perform the ablation procedure." Apparently piqued by my agitated protestation, Dr. Swerdlow dismissively replied "how do you think we train doctors." I shot back indignantly, "not by killing Nadine!" This exchange is all but memorialized in Dr.

Swerdlow's addendum to the In-Patient Ablation Procedure Notes (Exhibit 12), where doctor Swerdlow registers my surprise at Dr. Cesario's unexpected participation in Nadine's ablation procedure.

53. Again and again, Dr. Swerdlow repeated that his understudy, Dr. Cesario, had operated on Nadine "under his supervision," as if these were somehow "magic words. This was my last telephone conversation with Dr. Swerdlow. The last thing he said to me was that Dr. Shivkumat wished to talk to me. I suggested that Dr. Shivkumar call me on Sunday evening at around 9:00 p.m.

54. At 9:00 p.m.on Sunday, 12 Seotember 2004, my cell phone rang. It was Dr. Shivkumar. My conversation with Dr. Shivkumar lasted about an hour. Dr. Shivkumar, repeated

**[Original: Page 11; 3.CT.804, 4.CT.970]**

much of what Dr. Swerdlow had already told me – that he had left the EP Lab sometime after the ablation procedure began to attend to another matter. Dr. Shivkumar then went on to spend a great deal of effort and energy praising his understudy, Dr. Cesario, and remarking on what an exceptional physician and "student" he was. As I did with Dr. Swerdlow, I pointed out to Dr. Shivkumar that neither Nadine nor I had ever heard of Dr. Cesario, and that Nadine had not agreed to Dr. Cesario's participation in her ablation procedure.

55. Dr. Shivkumar and I also spent some amount of time discussing the experimental procedure that was performed on Nadine (and other patients). I once again

voiced my reservations about the application of an anesthesiologist's temperature probe to a use for which it was not intended or designed. Like Dr. Swerdlow, Dr Shivkumar did not respond to this concern. Dr, Shivkumar expressed regret over Nadine's death and our conversation ended.

56. After I verified the evidence of Nadine's brain death, her life support was disconnected on 12 September 2004. An autopsy that was performed on her confirmed that her death resulted from the complications due to an atrio-esophageal fistula.

57. I set out to inquire into the details of Nadine's death. I made several e-mail inquiries of Dr. Swerdlow about the experiment that Nadine had been subjected to and about the specific temperature probe employed. This e-mail dialog is attached as Exhibit 9. There Dr. Swerdlow confirms that Nadine was subjected to his experimental esophageal temperature monitoring experiment.

58. Moreover, a review of the e-mail communication between Dr. Swerdlow and myself showed that neither Dr. Swerdlow nor Dr. Shivkumar knew anything about the operating and performance characteristics of the temperature probe they employed during Nadine's ablation therapy, for purposes of monitoring esophageal temperature. Dr. Swerdlow also confided that there was no known esophageal temperature measure which served to indicate when to terminate power to the ablation catheter in order to avoid the atrio-esophageal fistula complication.

59. In February 2005 I learned that Dr. Swerdlow, Cesario and Shivkumar had published the results of their

esophageal temperature monitoring experiment (Exhibit 7) and in June 2005, II

**[Original: Page 12; 3.CT.805, 4.CT.971]**

learned that Dr. Swerdow had presented the results of the temperature monitoring study at the 2005 ACC (American College of Cardiology) Annual Scientific Session (Exhibit 8). There Dr. Swerdlow proclaimed, thet "no acute or chronic complications" had occurred during the study. Apparently, Dr. Swerdlow didn't think that the loss of Nadine's life was "acute" or "chronic" enough to deserve mention.

60. But, Nadine's informed consent was never sought nor granted before she was subjected to the esophageal temperature monitoring experiment, as is required under UCLA rules and regulations regarding human experimentation and as stipulated in the UCLA Human Research Investigator's Manual (Exhibit 11). In Section 4 of that document the stringent requirements for informed consent of subjects in human experiments is spelled out. In Section 7, at page 7-1 is found the prerequisite that investigators are required to obtain Institutional Review Board approval if, among other things, the conduct or recruitment of the research involves institutional resources (property, facilities or funding, including extramural funds administered by UCLA).

61. But, according to my conversations with Drs. Swerdlow and Shivkumar, they did none of these things. Then in May 2006, I learned for the first time, from Douglas Packer, M.D., defense expert witness, that the ablation procedure performed on Nadine was not the one she had

consented to. Dr. Packer identified the ablation procedure performed on Nadine as a wide area circumferential or Pappone technique. The ablation procedure Nadine consented to was the Empirical Wide Area Pulmonary Vein Isolation procedure. I compared the description that Dr. Swerdlow had give Nadine and I of the Empirical Pulmonary Vein Isolation Procedure with the Pappone technique as it was described in Exhibit 12, the UCLA In patient Procedure Notes for Nadine's ablation procedure. I could see that these are very different approached to ablative therapy. The one Nadine consented to was a picture of simplicity while the one that was performed on her appeared to burn tissue needlessly. This revelation has necessitated a much broader scope of discovery that was originally envisioned, and Plaintiffs outstanding discovery requests reflects this new reality.

62. In summary, Drs. Swerdllow and Shivkumar promised Nadine that they would

**[Original: Page 13; 3.CT.806, 4.CT.972]**

cure her arrhythmia with a conservative approach, an Empirical Pulmonary Vein Isolation procedure. Instead they performed the Pappone technique, to which Nadine did not consent, they substituted an inexperienced trainee electrophysiologist, Dr. David Cesario, for Dr. Shivkumar, without Nadine's knowledge or consent, and they subjected Nadine to a medical research experiment, without obtaining her informed consent. In so doing, they fatally injured her and wrongly deprived Nadine of her life.

I declare under the penalty of perjury, under the

laws of the State of California, that the foregoing is true and correct.

Executed this 25th day of July 2006 at Dove Canyon, California.

/ Original Signed /

Valer V. Secarea, Jr.
Declarant

**18 September 2003 email between Dr. Swerdlow and Nadine discussing how Drs. Swerdlow and Shivkumar work as a team**

(Italicized text is from Nadine's original email to Dr. Swerdlow. Dr. Swedlow's responses, unitalicized, follow, as in the original email he sent back to Nadine.)

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**[Original: Page 1; 3.CT.852, 4.CT.988]**

X-From_: swerdlow@ucla.edu Thu Sep 18 13:46:18 2003
X-Sender: swerdlow@mail.ucla.edu
Date: Thu, 18 Sep 2003 13:22:36 -0700
To: Val Secarea <vsecarea@arts-n-engineering.com>
From: Chuck Swerdlow <swerdlow@ucla.edu>
Subject: Re: Ablation
X-Scanned-By: MIMEDefang 2.25 / SpamAssassin 2.43 / mail.ucla.edu
X-Probable-Spam: no
X-Spam-Hits: -3.3

*Dr. Swerdlow:*

*Thank you so much for your prompt reply to our questions.*

*We've discussed the catheter ablation procedure at length. If I were to undergo it, we'd like you to perform it along with the colleague you mentioned from UCLA. We'd prefer to have it done at Cedars Sinai. By the way, I'd be interested in knowing which part(s) of this procedure each of you would be performing.*

Dr. Shivkumar does not work at Cedars Sinai, so I cna do the procedure myself at Cedars or we can work together at UCLA.. Each of us is qualified to do all parts of the procedure. What we do when we work together varies from case to case.

*Meanwhile, since I've only been taking Norpace CR for a little under two weeks (with some positive results) I'd like to give it additional time. If I understand Dr. Brodsky correctly, he seems to believe that if Norpace CR doesn't help (or stops helping), the catheter ablation is advisable. So, we'd like to know:*

*1) How far in advance we should schedule a catheter ablation with you and your colleague.*

Two months is best.

*2) How soon you think I should have an echo-cardiogram (and any other preliminary lab work) performed.*

After you schedule.

*3) If a follow up visit with you would be advisable/necessary, to discuss and plan for the procedure itself.*

Whatever you prefer.

**[Original: Page 2; 3.CT.853, 4.CT.989]**

Chuck Swerdlow

*Nadine Secarea*

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**1 December 2003 email between Dr. Swerdlow and Nadine re: choice of surgical team**

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**[Original: Page 1; 3.CT.859, 4.CT.995]**

Date: Mon, 01 Dec 2003
To: swerdlow@ucla.edu
From: Val Secarea <vsecarea@arts-n-engineering.com>
Subject: Scheduling A Catheter Ablation

Dr. Swerdlow:

My husband and I have talked it over and have decided that I should definitely go ahead with a catheter ablation. If possible, we'd prefer it to be done by you and Dr. Shivkumar from UCLA. If this isn't possible, then perhaps with Dr. Gang, as you suggested in a previous e-mail.

Please tell us what we need to do to prepare the way for this procedure, and how long it will be before it can be performed. I'd like to get started on the preparations as soon as possible because the Norpace CR doesn't seem to be consistently providing the relief I believe it should and one of its side effects has been the return of an inner ear problem that I've experienced from time to time. This problem is affecting my quality of life. To try to alleviate it, Dr. Brodsky had suggested reducing the dose from 100 mg twice/day to 100 mg once/day. I've tried doing this, but the arrhythmias only stop temporarily (a few days or so) and then they return. So, I have to return to the original dosing schedule. This is the fourth medication that's been tried since 2000 (when the arrhythmias began) and no other medicine has been suggested. All of this, plus our understanding that an ablation has at least a 70% chance of

eradicating my arrhythmias, finally convinced us to go ahead with this procedure.

By the way, if I'm suffering from Syndrome-X, would that in any way affect me during or after the ablation? One of the matters I've been trying to resolve before having an ablation is whether I have this condition, as was suggested by Dr. Michael Moran while I was in Saddleback Hospital in Laguna Hills. Since this was and is a complete surprise to me, I pursued a second opinion from Dr. Alan N. Elias at the UCI Medical Center. The results of a blood test he ordered have indicated that I don't have diabetes. However, Dr. Elias has said that additional testing must be done to determine whether I'm insulin resistant. He didn't appear to give much weight to the glucose tolerance test that was done while I was at Saddleback Hospital. As I understand it, this was because the test didn't track the levels of both insulin and glucose.

Meanwhile, we'd like to know if something like a "Catheter Ablation Patient's Checklist and Guide" is available. If it isn't, we'd like to have some additional information so we can develop our own "checklist" of tasks and considerations. Specifically, we'd like to know:

(1) Who do we contact for information about the cost(s) of this procedure? I assume that Blue Cross covers catheter ablations, but I'd like to know if there's anything that's not covered.

**[Original: Page 2; 3.CT.860, 4.CT.996]**

(2) I'm wondering if taking Norpace CR may interfere with the ability to see (and map) the arrhythmias "in action." So, I'd like to know if I'll need to stop taking the Norpace before the procedure is performed. If so, when should I stop it?

(3) Is catheter ablation an outpatient procedure, or will I be admitted to the hospital for some specific length of time?

(4) We'd like to know who is supposed to schedule the ablation and the "hospital stay." Can I do this? If, so who do I contact? I'd like to have an opportunity to "plan ahead" to the maximum extent possible.

(5) What additional tests need to be performed before the ablation can be done?

(6) Should I make an appointment to see you before the day the procedure is scheduled?

(7) Assuming that I'll be admitted to a hospital facility to have the ablation done, I'd like to know what I can expect to happen, once I'm admitted. For example --

> (a) How I will be prepared for the ablation (physically and informationally), and who will be doing the preparation?
>
> (b) Will I see you in the hospital before (and/or after) the ablation?
>
> (c) Will I have an opportunity to talk to the

anesthesiologist beforehand?

(d) Will I be awake during the procedure?

(e) How likely is it that the EP study you'll perform will identify (and lead to the ablation of) ALL the current sources of my arrhythmia, assuming there's more than one source?

(f) Where will I be taken after the ablation is over, and what happens next?

(g) How long will I be in the hospital?

(h) Can Val stay with me at the hospital, overnight? (We live about 75 miles from either Cedars Sinai or UCLA).

(i) Will you be giving me any instructions about "after care" and what to expect during the recovery/healing process, when I'm ready to be discharged?

(8) I understood, from your previous e-mail, that there's a 25% chance I'll experience arrhythmia(s) after the ablation is performed.

If I do develop arrhythmia(s) will I have to continue on Norpace or can we re-introduce Atenolol? Atenolol worked for over a year, and the side effects were tolerable.

How long should I expect any post-ablation arrhythmias to continue?

What would we do if it/they continue beyond that point?

(9) For "housekeeping" purposes I'd also like to know:

(a) Did I provide you with a list of the medications to which I'm allergic or have had significant reactions? If not, please let me know your fax number so I can send it to you.

(b) Did your office receive the records from Saddleback Hospital? (You may recall that we were awaiting their arrival, by fax, on the day I had my appointment with you.)

Thank you for your past assistance and, thank you, in advance, for your anticipated reply.

**[Original: Page 3; 3.CT.861, 4.CT.997]**

Nadine Secarea

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**October 2004 email correspondence between Valer and Dr. Swerdlow re: esophageal temperature sensing performed on Nadine**

(Italicized text, is from Valer's email to Dr. Swerdlow, while Dr. Swerdlow's responses are unitalicized. The email sequence order is "bottom-up.")

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**[Original: Page 1; 4.CT.912, 4.CT.1048]**

Date: Tue, 12 Oct 2004
To: Val Secarea <vsecarea@arts-n-engineering.com>
From: Charles Swerdlow <swerdlow@ucla.edu>
Subject: Re: Esophageal Temperture Sensing

Dear Mr. Secarea,

Even though it has been a long day, I'd like to send you a brief reply to your main question.

But first, I don't know any more details about the Vital Temperature probe than I supplied to you. Apparently it is a standard esophageal temperature probe used at UCLA.

There are no published (or to the best of my knowledge) unpublished esophageal-temperature data on which to base decisions about termination of radiofrequency energy delivery during left atrial ablation. Up to the time of Nadine's case, our empirical policy was to stop ablation for an abrupt (>0.5° C) rise in esophageal temperature. After termination of radiofrequency energy, the esophageal temperature continues to rise for about 30 seconds due to conduction of previously applied heat energy.

Prior to Nadine's case, we had recorded esophageal temperature and correlated it with radiofrequency applications in 13 patients. Eleven of these patients had esophageal temperature rises >0.5° C . In these patients, the maximum increase in temperature was 1.3 ± 0.4° C

(range 0.8 - 1.6°). In Nadine's case the maximum temperature rise was 1.2° (from 37.1° to 38.3°).

The output from the esophageal temperature probe is a digital display, but it is not recorded electronically (in contrast to catheter tip temperatures during radiofrequency ablation).

I hope this is helpful.

Sincerely,

Chuck Swerdlow

*Dr. Swerdlow,*

*Thanks for the information you supplied.*

*I could not find the performance specifications for the Vital Temp 1011-18 Fr Stethoscope series 400 device on the Vital Signs Inc. website. Evidently, I'll need to contact the manufacturer directly for this information. Hopefully, they will provide it to me.*

*However, I do need some additional data from you. What were the esophageal temperature values/ranges at the time Nadine was undergoing the ablation (the "burn"), as indicated by the Vital Signs, Inc. device? And, what temperature value did you consider to be of sufficient magnitude to be be regarded as an "alarm" or "indicator" that there may be a danger of fistula*

**[Original: Page 2; 4.CT.913, 4.CT.1049]**

*formation from the ablation activity?*

*Once again, thanks for your help. At some point, I will probably take you up on your offer to assist me with a literature search on the biophysics of RF ablation.*

*Val Secarea*

At 10:17 AM 10/6/2004 -0700, Chuck Swerdlow wrote:

Dear Mr. Secarea,

Thank you for your e-mail. I have not had the opportunity to talk with to you since Nadine's death. Please accept my condolences for your loss.

With regard to the two specific questions you ask:

(1) Dr. Shivkumar provided me with the model number of the esophageal temperature probe used in your wife's ablation. It was

VITAL-TEMP
Ref: 1011-18Fr
series 400

The manufacturer is
Vital Signs Inc:

20 Campus Road
Totowa, NJ 07512
1-800-932-0760
Fax: 973 790 3307
www.vital-signs.com

Their home page redirects you to
http://home.vital-signs.com/home/homepage.asp

The probe is listed on this page:
http://www.vital-signs.com/domino/HTML/Public%20Side/Brochurelibrary.nsf/3cf90a23430db5a9852562840073ae37/c68d43008c77fe0685256a56005146de?OpenDocument

(2) There is an extensive literature about the biophysics of RF ablation in relation to features such as electrode size, power, temperature, and blood flow. I don't understand your specific question in parentheses, but I would be pleased to discuss it with you. I can also assist you with a literature search.

On a related subject, my secretary Randi received your request for my medical records on Nadine. She has copied them and will mail them today. After Nadine's stroke, I reviewed the electrophysiology lab computer records from her ablation. These include the temperature and power records for each ablation. I have included printed temperature and power records for ablations on the posterior wall of the left atrium near the esophagus.

Please let me know if I can provide you with any additional

information or be of assistance in

**[Original: Page 3; 4.CT.914, 4.CT.1050]**

any way. I would be pleased to talk to you if that would be helpful.

Chuck Swerdlow

*Dr. Swerdlow:*

*In one of the conversations we had during the time Nadine was in the ICU at Irvine Hospital, you explained to me how you had placed a temperature sensor in Nadine's esophagus to detect conditions which might indicate atrio-esophageal fistula formation. Your efforts have kindled my "engineering curiosity" about this subject, but I find my efforts to explore it further at an impasse because of a lack of specific information. So, I'm asking for your help in providing the following:*

*(1) Who is the maker and what is the model number of the temperature sensing apparatus that placed in Nadine's esophagus?*

*(2) Do you know of any clinical or research studies which have determined the temperature ranges of tissue undergoing RF ablation? (i.e., Is there a temperature differential that can be "sensed" and how long does the phenomenon, if any, last?)*

*Thanks for your help.*

*Val Secarea*

Charles Swerdlow MD
Cardiac Electrophysiology
Clinical Professor of Medicine UCLA
Cedars Sinai Medical Towers
8635 W Third St, Ste 1190 W
Los Angeles, CA 90048-6101
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**[Original: Page 4; 4.CT.915, 4.CT.1051]**

Phone 310 652-4600
Fax 310 659-8387

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**Abstract of the temperature probe device experiment at issue in this case, presented at the 2005 American College of Cardiologists Scientific Session, 8 March 2005: Cesario D, Shivkumar K, Valderrabano M, Wiener I, Swerdlow C., Esophageal temperature monitoring during left atrial catheter ablation for atrial fibrillation. *J Am Coll Cardiol* 2005;45 Suppl A:114A**

This transcription obtained from the on-line ACC 2005 conference abstracts, still available from:

http://www.abstractsonline.com/viewer/viewAbstract.asp?CKey={1BB80FBE-4DFF-4B01-B2B3-3D5F3116C011}&MKey={01BF70A7-CBFB-4EA8-A9F0-6A7C23C53D59}&AKey={7455DAE5-72D2-487B-A9CA-C5758F04C24E}&SKey={262FB16E-C71E-4EA1-B052-C06B2D813C33}

The on-line description of the research at issue in this case is the same as the Clerk's Transcript copy [4.CT.903-904; 4.CT.1039-1040] that was taken directly from the JACC publication: Cesario D, Shivkumar K, Valderrabano M, Wiener I, Swerdlow C., Esophageal temperature monitoring during left atrial catheter ablation for atrial fibrillation. *J Am Coll Cardiol* 2005;45 Suppl A:114A -- but much more easily transcribed into this appendix.

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**Presentation Number:** 838-8

Abstract Title: Esophageal Temperature Monitoring During Left Atrial Catheter Ablation for Atrial Fibrillation

**Presentation Start/End Time:** Tuesday, Mar 08, 2005, 9:45 AM -10:00 AM

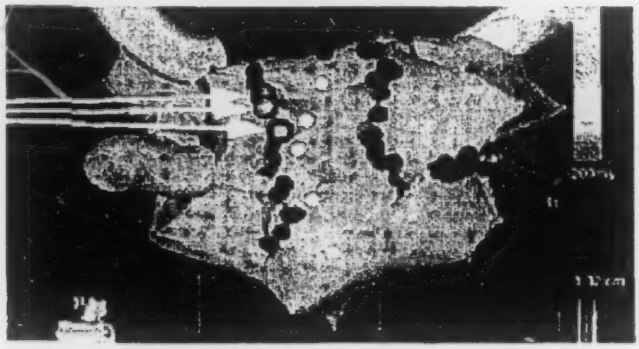
**Topic:** Clinical Electrophysiology--Supraventricular Arrhythmias

**Author Block:** David Cesario, Kalyanam Shivkumar, Miguel Valderrabano, Isaac Wiener, Charles Swerdlow, UCLA Medical Center, Los Angeles, CA, Cedars Sinai Medical Center, Los Angeles, CA

**Background:** Left atrial (LA) - esophageal (ESO) fistula is a life-threatening complication of LA radiofrequency catheter ablation (CA) for atrial fibrillation. We hypothesized that monitoring of ESO temperature (T) may detect early T rises to prevent ESO injury. Methods: We inserted an ESO T probe during LACA in 12 pts. The course of the ESO was marked on electroanatomic maps at the closest points on biplane fluoroscopy. The T probe was positioned at the level of the 8-mm ablation tip for lesions on the posterior wall or roof, where maximum power and T were 40 - 50 W/50 - 55°. We stopped ablation for an abrupt rise in ESO T >0.5°. Results: Abrupt ESO T rises occurred in 11 pts (92%) at 1 - 4 locations after 15 - 60 sec of ablation. ESO T rose for ~ 30 sec after termination of ablation by a

maximum of 1.3 ± 0.3° (range 0.8 - 1.6°). Ablation sites with ESO T rises corresponded to the course of the ESO on electroanatomic maps, but were part of 3 different sets of linear lesions: LA-roof ablation line (2 pts) or encircling lines around left-sided (7 pts) or right-sided (2 pts) pulmonary veins. The Figure shows a typical electroanatomic map (posterior-anterior projection) with ablation sites (black), ESO (white), and sites of T rise (arrows). There were no acute or chronic complications. Conclusions: ESO T rises abruptly during LACA at sites adjacent to the ESO. T rises were associated with 3 different lesion sets. The maximum T rise was small when ablation was stopped for a T increase of 0.5°. Monitoring ESO T may reduce the risk of LA-ESO fistula.

ESO T rise



**Commercial Relationship:**

D. Cesario, Medtronic H; Pfizer B; K. Shivkumar, St Jude E; Medtronic H; M. Valderrabano, Medtronic H; I. Wiener, Medtronic H; Guidant H; C. Swerdlow, Medtronic E; St Jude E.

**Review, by Jamie Conte, M.D., of the temperature probe device experiment at issue in this case , presented at the 2005 American College of Cardiologists Scientific Session, 8 March 2005., published in the *Journal of the American College of Cardiologists* (JACC) Vol. 45, No. 11 Suppl B, ACC 2005 Annual Session Highlights June 7, 2005:30B–2B**

Original journal article review available at:

http://content.onlinejacc.org/cgi/reprint/45/11_Suppl_B/B30.pdf

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**[Original: Page 1; 4.CT.899, 4.CT.1035]**

Finally, Cesario et al. (13) (presented by Charles Swerdlow) hypothesized that monitoring of esophageal temperature may detect early temperature rises to prevent esophageal injury. They studied 12 patients using an esophageal temperature probe positioned at the level of the 8-mm ablation tip. Maximum power and temperature were 40 to 50 W/50° to 55°. Ablation was terminated when there was an abrupt rise in esophageal temperature ( 0.5°). Esophageal temperature rose in 11 patients (92%), although they had no acute or chronic complications. The researchers concluded that esophageal temperature rises abruptly during LA catheter ablation at sites adjacent to the esophagus and that monitoring the esophageal temperature may reduce the risk of LA-esophageal fistula.

An enormous amount of scientific information was presented at this year's Scientific Sessions, making it impossible to recognize the efforts of each investigator and the contributions each one made to the success of the Clinical Cardiac Electrophysiology Section. The aforementioned presentations were also formally offered at the "Highlights" sessions on Wednesday, March 9, 2005.

---

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13. Cesario D, Shivkumar K, Valderrabano M, et al. Esophageal temperature monitoring during left

atrial catheter ablation for atrial fibrillation (abstr). J Am Coll Cardiol 2005;45 Suppl A:114A.

**Motion and Request for Judicial Notice (RFJN) filed in the California Court of Appeal requesting notice of, among other things, FDA Regulations and that agency's interpretation thereof**

Note that the original motion filed in the California Court of Appeals is a "digital document" and included a CD on which the materials referred-to in this transcription were contained. However, the Rules of this court seem to make no provision for such a submission in a Petition. Consequently, the CD (even though they were actually produced) was omitted, in order not to create a question of propriety regarding this filing.

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COURT OF APPEAL
OF THE STATE OF CALIFORNIA
FOURTH APPELLATE DISTRICT
DIVISION THREE

VALER V. SECAREA, JR.,
Plaintiff and Appellant,
v.
REGENTS OF THE UNIVERSITY
OF CALIFORNIA, et al.,
Defendants and Respondents

Appeal from Judgments entered on or about August 15, 2006, Orange County Superior Court, Case No. 05CC10019
Hon. William Monroe, Judge Presiding

DIGITAL DOCUMENT

# MOTION AND REQUEST FOR JUDICIAL NOTICE

Evidence Code § 459; Rule 8.252, California Rules of Court

Valer V. Secarea, Jr.
12 Amberwicke
Dove Canyon, CA 92679
949-589-3843
760-809-3095

Plaintiff and Appellant,
in Propria Persona

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UCLA 1997 Investigator's Manual for the Protection of Human Subjects (All) . . . . . 41

UCLA 2006 Investigator's Manual for the Protection of Human Subjects . . . . . 40, 43

University of California Berkeley, Human Research Protection Program Policies and Procedures . . . . . 32

University of California Berkeley, Federalwide Assurance (FWA) for Protection of Human Subjects . . . 33

University of California Contract & Grant Manual . . . . . 33, 38

University of California, Los Angeles Office for Protection of Research Subjects Standard

Operating Procedures (SOPs) . . . . . 40

**SCIENTIFIC LITERATURE**

ACC 2005 Respondent Researchers' Presentation Abstract . . . . . 10, 30, 43, 50, 51

ACC 2005 Scientific Session Review . . . 9,10 30,43,50 51

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David, Y, et. al., Issues Associated with Off Label Use of Medical Devices, Proceedings of the 29th Annual International Conference of the IEEE EMBS, Cité Internationale, Lyon, France August 23-26, 2007 . 48

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Gazarian, M., et.al., Off-label use of medicines: consensus recommendations for evaluating appropriateness, MJA 2006; 185 (10): 544-548 . . . . . 45

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Health Plan of New York Off-Label Use of FDA-Approved Drugs . . . . . 47

Off-label drugs and medical devices: Get the facts (Mayo Clinic) . . . . . 44

Pappone C, et. al., Atrio-esophageal fistula as a complication of percutaneous transcatheter ablation of atrial fibrillation. *Circulation*. 2004;109: 2724–2726 . . . . . 55

Redfearn DP, et. al., Esophageal temperature monitoring during radiofrequency ablation of atrial fibrillation. *J Cardiovasc Electrophysiol*. 2005 Jun; 16(6): 589-93 55

Sonmez B, et. al., A fatal complication due to radiofrequency ablation for atrial fibrillation: atrio-esophageal fistula. *Ann Thorac Surg.* 2003;76:281–283 . . . . . 56

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## CASES FOR WHICH JUDICIAL NOTICE IS SOUGHT

*Anderson v. George H. Lanier Memorial Hosp.* (11th Cir. 1993) 982 F. 2d 1513 . . . . . 52

Barrett v. United States (2nd Cir. 1982) 689 F.2d 324 . . . . . 52

*In Re Cincinnati Radiation Litig.* (S.D. Ohio 1995) 874 F. Supp. 796 . . . . . 52

*Kus v. Sherman Hospital* (Ill. App. Ct. 1995) 644 N.E.2d 1214 . . . . . 53

*Spenceley v. M.D. Anderson Cancer Ctr.* (S.D. Tex. 1996) 938 F. Supp. 398 . . . . . 53

## LAW REVIEWS FOR WHICH JUDICIAL NOTICE IS SOUGHT

Morreim, E., Medical Research Litigation and Malpractice Tort Doctrines: Courts on a Learning Curve, 4 *Hous. J. Health L & Pol'y* (2003) . . . . . 51

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## I. DIGITAL DOCUMENT SET-UP

This motion exists both in paper (filed with the Court) and electronically, on the enclosed CD-ROM.

*It is the electronic version of this document on CD-ROM which is of interest.* Almost all the records which are the subject of this motion are retrieved from various state and federal government as well as academic and informational web sites, by clicking on the blue hyperlinks in the electronic (PDF) version of this motion. The documents so retrieved will be opened in your internet browser. Either Firefox or Microsoft Internet Explorer should work.

To set-up and interact with the active digital version of this document and retrieve the records which are the subject of the motion:

(1) You must be connected to the Internet

(2) Sign on to FindLaw (It's not Lexis, but it's free. Note that case opinions which are not hyperlinked could not be located on the "fee web." No attempt was made to link to Lexis, given that there was no time to link to and test its specialized interface.)

(3) Place the enclosed CD-ROM in your CD-ROM or DVD drive.

(4) With Windows Explorer, drag the "G037651-Root-Directory" folder from the CD to the "C:" root directory to your PC hard drive, so that you now have a "C:/G037651-Root-Directory" on your PC. (That is, copy G037651-Root-Directory from the CD to your C: drive. The

reason for this is an apparent limitation in the behavior of hyperlinks in WordPerfect, the wordprocessor used to generate this document.)

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(5) From Windows Explorer:

(a) click on C:/G037651-Root-Directory to "open" it

(b) double click on: G037651 Appellant Request For Judicial Notice.pdf

(6) This will open the active document in your Acrobat PDF reader.

(7) Hyperlinks to documents are indicated by underlined blue text.

(8) Clicking on the link opens the document or web page in your internet browser. (At least that's how it works with Firefox.).

(9) WordPerfect only opens documents. You must close them (at least on my computer).

(10) Almost all of the documents which are the subject of this request are retrieved from the Internet.

(11) The documents that have a companion copy on CD (now on your hard drive) will so indicate with an [OnDisk] hyperlink.

(12) If a scientific paper PDF document does not immediately appear, click "Begin Manual Download"

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on the displayed PDF download page or access the local

copy by clicking the [OnDisc] hyperlink.

(13) Once opened, retrieved documents can be read or saved.

(14) To remove the C:/G037651-Root-Directory and all of its contents, click on it (select it), then from the File menu, click delete (or press the DELete key).

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## II. INTRODUCTION AND POINTS AND AUTHORITIES

Pursuant to Evidence Code § 459 and Rule 8.252, California Rules of Court, Appellant hereby moves the Court to take judicial notice of the matters and documents, as described herein.

An appellate court may consider matters that are properly the subject of judicial notice.(Evidence Code § 459; *Crowley v. Katleman* (1994) 8 Cal.4th 666, 672; *Evans v. Pillsbury, Madison & Sutro* (1998) 65 Cal.App.4th 599, 605, fn. 5.) Moreover, under Evidence Code § 459 appellate courts have the same right and power to take judicial notice as do the trial courts. (*Smith v. Rae-Venter Law Group* (2002) 29 Cal.4th 345, 359; *People v. Connor* (2004) 115 Cal.App. 4th 669, 681 fn.3; Evidence Code § 454(b); 2 Jefferson, Cal. Evidence Benchbook (3d ed. 1997) § 47.68, at p. 1093.)

The underlying theory of judicial notice is that the matter being judicially noticed is a law or fact that is not reasonably subject to dispute. (Evidence Code § 451(f); *Post v. Prati* (1979) 90 Cal.App.3d 626, 633.)

In particular, judicial notice under Evidence Code § 452, is intended to cover facts that are not reasonably subject to dispute and are easily verified. These include, for example, facts that are widely accepted as established by experts and specialists in the natural, physical, and social sciences which can be verified by reference to treatises, encyclopedias,

almanacs, and the like or by persons learned in the subject matter. (*Gould v Maryland Sound Industries, Inc.* (1995) 31 CalApp.4th 1137 [37 Cal Rptr 2d 718]). Matters of scientific certainty are subject to judicial notice. (*McAllister v Workers' Comp. Appeals Bd.* (1968) 69 Cal.2d 408 [71 Cal Rptr 697, 445 P.2d 313]). In matter involving extensive evidence on insulin, which was allegedly injected to kill, it was proper for the court to consult textbooks concerning the nature of the properties of insulin, as the court is entitled to take judicial notice on its own of the expertise of doctors testifying at the trial. (*People v Archerd* (1970) 3 Cal.3d 615 [91 Cal Rptr 397, 477 P.2d 421]). It is a matter of general knowledge that a sudden shock can produce injury to the nervous system. (*Windeler v Scheers Jewelers* (1970) 8 CalApp.3d 844 [88 Cal Rptr 39]). Judicial notice may be taken of the fact that coronary arteriosclerosis amounts to "heart trouble." (*Knowles v Workers' Comp. Appeals Bd.* (1970) 10 CalApp.3d 1027 [89 Cal Rptr 356]).

Regulation or legislative enactment issued by or under the authority of the United States or any public entity in the United States may be subject to judicial notice. (Evidence Code § 452(b)).

A death certificate is within the provision of Evidence Code § 452, that judicial notice may be taken of official acts of the legislative, executive, and judicial departments of a state and of facts and propositions that are not

reasonably subject to dispute and are capable of immediate and accurate determination by resort to sources of reasonably indisputable accuracy. (*People v Terry* (1974) 38 Cal App 3d 432 [113 Cal Rptr 233]).

Courts may take judicial notice of information provided online. Appellate courts have increasingly cited information found online. As with hard-copy publications, courts are most willing to take judicial notice of information found on government Web sites, such as the time of sunrise found on the Web site of the U.S. Naval Observatory (*U.S. v. Bervaldi* (11th Cir., 2000) 226 F.3d 1256, 1266 n.9); the prime interest rate on the Federal Reserve Board Web site (*Levan v. Capital Cities/ABC Inc.* (11th Cir. 1999) 190 F.3d 1230, 1235 n.12); and records of retired military personnel on a federal Web site (*Denius v. Dunlap* (7th Cir. 2003) 330 F.3d 919, 926).

Courts have also been willing to take judicial notice of information on commercial Internet sites, including mileage information on Mapquest (*In re Extradition of Gonzalez* (W.D. La. 1999) 52 F. Supp. 2d 725, 731 n.12); historical information on Liberia on the "Geocities" Web site (*Bridgeway Corp. v. Citibank* (S.D.N.Y. 1999) 45 F. Supp. 2d 276, 278 n.2); and information regarding a bank's ownership from the bank's Web site (see *Laborers' Pension Fund v. Blackmore Sewer Constr. Inc.* (7th Cir. 2002) 298 F.3d 600, 607).

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It is noteworthy that the United States Supreme Court has characterized the Internet as "a vast library

including millions of readily available and indexed publications ...." (*Reno v. American Civil Liberties Union* (1997) 521 U.S. 844, 853; *In re Stevens* (2004) 119 Cal.App.4th 1228, 1234- 1235.)

In California, a court has discretion to take judicial notice of "[f]acts and propositions that are not reasonably subject to dispute and are capable of immediate and accurate determination by resort to sources of reasonably indisputable accuracy" (Evidence Code § 452(h)). If this standard is satisfied, judicial notice may be taken of information obtained from the Internet. (*Boghos v. Certain Underwriters at Lloyd's of London* (2005) 36 Cal.4th 495, 505-506, fn. 6; *Walt Rankin & Associates, Inc. v. City of Murrieta* (2000) 84 Cal.App.4th 605, 623-624, fn. 12.)

In the case at bench, the materials listed *infra*, most of which are available on-line, shed considerable light on the circumstances leading and requirements of researchers engaging in surreptitious medical experimentation in a clinical setting, as has been alleged in the complaint.

Each document for which judicial notice is sought is described and its relevance explained.

Finally, some or most of the documents included in this motion are copyrighted, even those that are otherwise freely available. Thus, for these



documents, distributed on the enclosed CD, "fair use" is claimed, pursuant to their use in a judicial proceeding. (United States Copyright Office, Circular 21, at page 6 [fair

use applied to "reproduction of a work in legislative or judicial proceedings"]; *Jartech, Inc. v. Clancy* (9th Cir. 1982) 666 F.2d 403, 406-07. See also *Religious Tech. Center. v. Wollersheim* (9th Cir. 1992) 971 F.2d 364, 367. ["[W]orks are customarily reproduced in various types of judicial proceedings . . . and it seems inconceivable that any court would hold such reproduction to constitute infringement either by the government or by the individual parties responsible for offering the work in evidence." 3 M. Nimmer & D. Nimmer, Nimmer on Copyright § 13.05[D] at 13-91 (1991)].

**[RFJN Original: Page 9]**

## III. MATTERS FOR WHICH JUDICIAL NOTICE IS REQUESTED

This litigation is, among other things, about a surreptitious human subject medical experiment performed by Respondent Researchers [1] on decedent Nadine Secarea

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[1] As before, parties are identified: appellant-plaintiff, Valer V. Secarea, Jr., ("Valer" or "Secarea") on behalf of himself and decedent wife, Nadine Francia Secarea ("Nadine"), defendants and respondents, Irvine Regional Hospital and Medical Center ("Irvine Regional"), Regents of the University of California ("Regents"); Kalyanam Shivkumar, M.D., David Cesario, M.D., and Charles Swerdlow., M.D., (In this motion, Regents and Drs. Shivkumar and Cesario are "UCLA Respondents" and Drs. Swerdlow, Shivkumar and Cesario are "Respondent Researchers").

It is noteworthy that "researchers" is how authors Kalyanam Shivkumar, M.D., David Cesario, M.D., and Charles Swerdlow., M.D., are referred to by their peers. (SAC §§ 206-

(SAC §§ 155-218/1.CT.113-129), without her knowledge or consent, causing or contributing to her death (SAC § 213/1.CT.127; 4.CT.946, 1082).

This motion provides publications, documents and records in aid of resolution of two closely-related issues in this case. The first group of referenced documents provides the basis for a showing that the human subject device experiment to which Nadine was subjected required, among other things, an IDE (Investigational Device Exemption) from the FDA as well as Nadine's informed consent, before the study could proceed. (See

**[RFJN Original: Page 10]**

generally, SAC §§ 44-88/1.CT.84-95) A second group of referenced documents provides the basis for a showing that Respondent Researchers did not possess the knowledge to utilize the medical device at issue in this case, an 18Fr 400 Series Esophageal Stethoscope Temperature probe, manufactured by VitalSigns, Inc., "off-label" and in a manner that is outside its design intent. (SAC §§ 71-74/1.CT.90-91; SAC §§ 194-199, Footnote 72/1.CT.123-124)

Original records which announced the results of Respondent Researchers' medical device study are: (1)

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208/1.CT.125-126; 4.CT.898-899; JACC 2005 Scientific Session Review [OnDisc] at page 32B). Consequently, it would seem most appropriate to refer to them collectively as "Respondent Researchers."

Respondent Researchers' ACC 2005-Presentation Abstract [OnDisc] and (2) JACC 2005 Scientific Session Review [OnDisc] where Dr. Jamie Conti reported that Respondent Dr. Swerdlow "hypothesized that monitoring of esophageal temperature may detect early temperature rises to prevent esophageal injury" and described the authors (Respondent Researchers) as "researchers," at page 32B.

## IV. JUDICIAL NOTICE OF CIVIL CODE § 3513 ISSUES

In this litigation, Respondent Regents and Respondent Researchers have argued that decedent Nadine Secarea somehow consented or could be considered to have consented, to the covert medical experimentation to which she was subjected and, by implication, waived statutory protections against such conduct. However, California does not permit such a result.

**[RFJN Original: Page 11]**

Civil Code § 3513 provides: "Any one may waive the advantage of a law intended solely for his benefit. But a law established for a public reason cannot be contravened by a private agreement." Under this principle, numerous agreements purporting to waive statutory rights designed primarily to serve a public purpose have been invalidated. (E.g., *County of Riverside v. Superior Court* (2002) 27 Cal.4th 793, 804-806 [statutory rights of employees not subject to blanket waiver]; *DeBerard Properties, Ltd. v. Lim* (1999) 20 Cal.4th 659, 668-669 [statutory prohibition

against deficiency judgment cannot be waived by agreement]; *Covino v. Governing Board* (1977) 76 Cal.App.3d 314, 322 [teacher's right to probationary status may not be waived]; *Cook v. King Manor and Convalescent Hospital* (1974) 40 Cal.App.3d 782, 792-793 [statutory prohibition of penalty and forfeiture provisions cannot be waived]; *De Haviland v. Warner Bros. Pictures* (1944) 67 Cal.App.2d 225, 234-236 [statutory time limitation on personal service contracts "may not be contravened by private agreement"].)

Consequently, documents which reveal how the statutory scheme might be applied to this case should be examined so as to ascertain whether an immutable public purpose precludes assumption of "agreements" to the contrary .

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## V. DOJ, FDA AND DHHS RESOURCES

The United States Department of Justice (USDOJ), the U. S. Food and Drug Administration (FDA) and U.S. Department of Health and Human Services (DHHS), DHHS Office for Human Research Protections (OHRP), publish on-line databases, guidance and official communications relevant to the issues addressed in this litigation. These resources are utilized in the hyperlinks throughout this document as sources of federal regulatory law as these might be applied to this case.

## A. On-Line Resources Used In This Document

1. United States Department of Justice
   DOJ Civil resource Manual, 110 Medical Device Law [2]

2. United States Code (USC) Title 21
   Cornell University Law School LII USC Title 21 Page

   Cornell University Law School LII FDCA Page

3. Code of Federal Regulations (CFR)

   Cornell University Law School LII CFR Search Page

   National Archives "Whole CFR" Page

4. Food and Drug Administration (FDA)
   CFR Title 21

   FDA CFR Title 21 Search Page

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FDCA to 21 USC Section Number Cross-Reference Table

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[2] Referenced at SAC Footnote 35/1 CT 86

5. FDA Web Documents

FDA Device Advice

Device Advice is FDA CDRH`s (Center for Devices and Radiological Health) self-service site for medical device and radiation emitting product information. It is an interactive system for obtaining regulatory information concerning medical devices and describes the requirements for human subject device experimentation.

FDA Significant Risk and Nonsignificant Risk Device Studies

Guidance intended to provide advice to sponsors, clinical investigators, and institutional review boards (IRBs) on how to determine the differences between significant risk and nonsignificant risk medical device studies. A significant risk study requires an IDE. The IRB (in this case, the UCLA IRB) must determine if a study is "significant risk."

FDA Investigational Device Exemption (IDE) for Clinical Studies

An approved IDE means that the IRB (and FDA) has approved the sponsor's study application and all the requirements under 21 CFR 812 are met. An investigational device exemption (IDE) allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data. IDE refers to the regulations under 21 CFR 812.

FDA IDE Application Form and Content

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Specifies the information content of an IDE application.

FDA Guide to Informed Consent

For studies that are subject to the requirements of the FDA regulations, the informed consent documents should meet the requirements of 21 CFR 50.20 and contain the information required by each of the eight basic elements of 21 CFR 50.25(a), and each of the six elements of 21 CFR 50.25(b) that is appropriate to the study.

FDA Frequently Asked Questions About Medical Devices

Guidance intended to assist clinical investigators and institutional review boards (IRBs) by answering common questions FDA receives concerning medical devices.

6. DHHS OHRP Web Documents

Human subjects research at University of California campuses is significantly regulated by DHHS OHRP Terms of Federalwide Assurances (FWAs) managed by DHHS OHRP. The many responsibilities of researchers is spelled out in the DHHS OHRP Human Research

Questions & Answers pages. Respondent Regents, in their operation of UCLA have agreed to the legal requirements and standards of care regarding human subjects research as stipulated in the UCLA (FWA) Assurance Policies. (See also 4.CT.922-933; 1058-1069; AOB:34) Respondent Researchers failed to follow these requirements.

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## B. FDA and DHHS OHRP Warning Letters

Warning letters, from both FDA and the DHHS OHRP, sent to medical researchers and investigators, including Respondent Regents, following on-site inspections, provide an "agency interpretation" of the meaning of the Federal Regulations regarding device experimentation on human subjects, as they would be applied to the circumstances which are at issue in this case.

Each reference to these public documents is hyperlinked to its originating source on the DHHS OHRP Warning Letters Index website or the FDA's Electronic Freedom of Information Reading Room website or from the United States Department of Justice.

"In the absence of express congressional intent, the interpretation of a statute adopted by the federal agency charged with enforcing it is entitled to great deference. [Citations.]" (See *Podolsky v. First Healthcare Corp.* (1996) 50 Cal.App.4th 632, 644, fn. 6.)

Under federal law, deference to an administrative agency's interpretation of a statute is mandatory under certain circumstances. (*Kruse v. Wells Fargo Home Mortg.*,

*Inc.* (2d Cir. 2004) 383 F.3d 49, 55, citing *Chevron, U.S.A v. Natural Res. Def. Council, Inc.* (1984) 467 U.S. 837, 843-844.) Deference is said to be mandatory "`when it appears that Congress delegated authority to the agency generally to make rules carrying

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the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority.'" (*Kruse, supra*, at p. 58, quoting from *United States v. Mead Corp.* (2001) 533 U.S. 218, 226-227; see also *Nat'l Cable & Telecomm. v. Brand X* (2005) 545 U.S. 967 [162 L.Ed.2d 820, 837-838].)

Moreover, "[T]he Legislature and the FDA, in their wisdom, have decreed that patients participating in clinical trials of investigational devices must be informed in writing, with a copy for themselves, of the nature of the trial and the device. Neither physicians nor courts are free to disregard these requirements." (*Daum v. SpineCare Medical Group, Inc.* (1997) 52 Cal.App.4th 1285, 1305 [61 Cal.Rptr.2d 260].)

### C. Specific FDA and DHHS OHRP Agency Interpretations

#### 1. Devices used by physicians in practice are "marketed"

Much of the language of the Federal Food, Drug and Cosmetics Act (FDCA or Act) deals with marketing and sale of medical devices. This language gives the impression

that the act applies only to those engaged in manufacturing and distribution. But, this is not the case. According to the FDA:

> Medical devices used by doctors in the course of their practice to treat patients are "marketed" and "held for sale" within the meaning of the Federal Food, Drug and Cosmetic Act (the Act).

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See the 11 July 2001 FDA warning letter to Paul E. Garland, M.D. [OnDisc], regarding use of a "gray market" laser in his medical practice. Consequently, the FDCA is equally applicable to even those engaged in the *practice of medicine*, as well as those manufacturing and distributing medical devices.

### 2. Researchers can be both sponsors and investigators

The FDA regulations regarding medical device experimentation apply to anyone conducting such studies. It is not limited to commercial companies, but includes the Respondent Regents and Respondent Researchers.

#### a. Physicians as sponsor-investigators

The following FDA warning letters were sent to physicians involved in medical device experimentation,

reviewing their non-compliance with applicable regulations, participating as both sponsors and investigators in medical device studies.

(1) 30 May 2008 FDA warning letter to Willa A. Hsueh, M .D., David Geffen School of Medicine at UCLA [OnDisc], where the FDA takes issue with Dr. Hsueh's conduct as sponsor-invetigator, and in particular requirements of informed consent (p.1, 5).

(2) 25 March 2004 FDA warning letter to Timothy A.M. Chuter, M.D. at the University of California at San Francisco [OnDisc], where the

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FDA reminds Dr. Chuter that he is both sponsor and investigator in his study (page 1; page 5, paragraph 4).

(3) 11 December 2003 FDA warning letter to Stephen H. Caldwell, M.D., University of Virginia Health Systems [OnDisc] (p. 1-3). [University researchers as sponsor-investigators.]

(4) 6 May 2008 FDA warning letter to Merrill Reuter, M .D., Ph .D. [OnDisc] (p.1-4). [Review of activities as both sponsor and investigator.]

(5) 18 December 2007 FDA warning letter to Bradley R. Wolf, M .D., Co-owner/Sponsor/Clinical Investigator [OnDisc] (p. 1-4).

**b. Universities as sponsors**

The 29 January 2007 FDA warning letter to the

University of Cincinnati College of Medicine [OnDisc], regarding their failure to comply with provisions of 21 CFR. Part 812 in conducting medical device experimentation as a sponsor.

### c. FDA regulations apply to "everyone"

Sponsors and investigators need not be commercial companies or in any way affiliated with a commercial company. The regulations that apply to the above-named physicians and institutions apply with equal force to Respondent Regents and Respondent Researchers. (SAC §§ 44-88/1.CT.84-95) But, as the Second Amended Complaint alleged, they did none of

the things the law required of them before subjecting decedent Nadine Secarea

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to a covert medical device study requiring IRB and FDA IDE approval as well as Nadine's informed consent. (SAC §§ 86-88/1.CT.94-95; also SAC Footnote 34/1.CT.86)

In *Quintanilla v. Dunkelman* (2005) 133 Cal.App.4th 95, 118-119, the court found that none of the physicians involved in that case had procured a legally effective informed consent. Consequently, the physicians were adjudged jointly responsible for this failure. In a similar fashion, neither Respondent Researchers nor Respondent Regents satisfied the conditions imposed by the FDA for human subject device experimentation in this case.

As a result, they should be likewise jointly responsible for the consequences of this failure. (See also the sections which immediately follow.)

### 3. IDE is required when testing safety & effectiveness

In the 25 June 2003 FDA warning letter to Gerald M. Burma, M.D., Parma Community General Hospital [OnDisc], (p.1), the FDA advised:

> Because your studies were conducted to determine the safety and effectiveness of using [redacted] in a manner not cleared by the FDA, you were required to have an FDA-approved IDE application before you could legally conduct such studies.

Respondent Researchers had neither applied for nor obtained an IDE from the FDA to test the safety and effectiveness of the Vital Signs probe in the role of atrio-esophageal fistula detection and prevention tool.

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(SAC §§ 187-199/1.CT.121-124) Consequently, the ablation procedure that incorporated that device study was unlawful, and Nadine's legally effective informed consent could neither be procured nor assumed. (See also the FDA Amended Administrative Complaint re: LAHayeSER [OnDisc], specifically describing application of IDE

requirements, IRB approval and informed consent, even for "home-grown" medical devices intended only for use in a purely private medical practice.)

**4. New Uses Require an IDE from the FDA**

Under FDCA § 201(h) [21 U.S.C. § 321(h)], products used pursuant to cure, mitigation, treatment, or prevention of disease, or to affect the structure or function of the body are considered to be medical devices. (3 January 2002 FDA warning letter to George G. Khouri, MD, PA [OnDisc] (p. 1)).

The intended use of a device is defined under 21 CFR 801.4. Notice or other information respecting the modification in the intended use of a device must be provided to the FDA as required by 21 CFR 807.81 (a)(3)(ii) and section 510(k) [21 USC § 360(k)] of the Act. A major modification in the intended use of a device as described at 21 CFR 807.81 (a)(3)(ii), requires the submission of a new application for pre-market approval (PMA) pursuant to section 515(a) [21 USC 360e], or an applications for investigational device exemptions (IDE) under section

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520(g) [21 USC 360j(g)] of the Act. (5 November 2001 FDA warning letter to Damon P. Miller, II, M.D. [OnDisc] (p. 2)).

A sponsor, is required to obtain a new IDE if a device that is approved for one indication is intended to be used in a clinical study for a new indication. (3 April 2007 FDA warning letter to Thomas P. Davis, M.D., St. John

Hospital and Medical Center [OnDisc](p. 2)).

The Second Amended Complaint alleges that the application of the Vital Temp probe at issue in this litigation is a new use as that is defined under the Act. To wit, the probe's FDA-approved intended use is measuring core body temperature during surgery, not protecting patients from atrio-esophageal fistulas during cardiac catheter ablations. (SAC §§ 191-192/1.CT.122)

Respondent Researches required UCLA IRB approval, Nadine's informed consent and an IDE from the FDA, in order to test the probe to see if will adequately perform in the manner envisioned by them. (SAC §§ 44-88/1.CT.84-95; SAC §§ 155-218/1.CT.113-129; 4.CT.898-899, 903-904; 1035-1036, 1039-1040)

### 5. Significant risk (SR) and Non-significant risk studies

The FDA publishes guidelines for IRBs and investigation significant and non-significant risk studies. (FDA Guidance for Institutional Review Boards and Clinical Investigators, "*FDA IRB SR/NSR Guidance*").

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A significant risk study requires an IDE from the FDA. Only the IRB (in this case, a UCLA IRB) can make an SR/NSR determination. Respondent Researchers, acting alone, could not. (See *FDA IRB SR/NSR Guidance*.) And, the UCLA IRB did not approve this study. (SAC §§ 86-88/1.CT.94-95)

Of the devices considered significant risk are "RF Catheter Ablation and Mapping Systems." (See *FDA IRB SR/NSR Guidance*, under "Cardiovascular," and just before "dental.").

The purported purpose of the Vital Temp probe at issue in this case was to locally "map" or indicate a hot spot in the esophagus during an ablation procedure. Respondent Researchers were required to submit to the UCLA IRB data to justify whether or not their study embraced significant risk, requiring an IDE from the FDA. (SAC §§ 80-82/1.CT.93) Neither Respondent Regents nor Respondent Researchers complied with this legal requirement. (SAC §§ 86-88/1.CT.94-95; also SAC §§ 83-84/1.CT.93-94; 4.CT.898-899, 903-904; 1035-1036, 1039-1040)

### 6. Assurance of scientific validity required for IDE applications

It is unlikely that Respondent Regents or Respondent Researchers could have procured an IDE, even if they applied. This is because the FDA requires an IDE application to be accompanied by data demonstrating

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safety and effectiveness, as the 2 March 2004 FDA warning letter to Ziyad M. Hijazi, M.D., University of Chicago [OnDisc], (p. 1) clearly states:

> ... conducted under a program designed to ensure that data and information contained

in requests for Investigational Device Exemptions (IDE) and Humanitarian Device Exemptions (HDE) submissions are scientifically valid and accurate. Another objective of the program is to ensure that human subjects are protected from undue hazard or risk during the course of scientific investigations. The aforementioned product used in studies are devices as that term is defined in Section 201(h) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 321 (h)].

An examination of the actual FDA IDE Application Form and Content confirms that a showing of scientific validity for the new intended device use, is required as element #2, of the IDE application:

> 2. Report of prior investigations (21 CFR 812.27);
>
> A report of prior investigations must include reports of all prior clinical, animal, and laboratory testing of the device. It should be comprehensive and adequate to justify the proposed investigation.
>
> Specific contents of the report must include:
>
> - a bibliography of all publications, whether adverse or supportive, that are relevant to an evaluation of the safety and

effectiveness of the device;

- copies of all published and unpublished adverse information;

- copies of other significant publications if requested by an IRB or FDA;

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- a summary of all other unpublished information (whether adverse or supportive) that is relevant to an evaluation of the safety and effectiveness of the device; and

- if nonclinical laboratory data are provided, a statement that such studies have been conducted in compliance with the Good Laboratory Practice (GLP) regulation in 21 CFR Part 58. If the study was not conducted in compliance with the GLP regulation, include a brief statement of the reason for noncompliance.

But, Respondent Researchers had *no data* to show, regarding their rationale for employing the Vital Temp probe in the manner used on Nadine, much less data that is "scientifically valid and accurate." (SAC §1 78/1.CT.119; §§ 191-195/1.CT.122-123)

7. Medical device evaluations are not "off-label" uses

Neither Respondent Regents nor Respondent Researchers addressed off-label use in their Motions for Summary Judgment, notwithstanding that it is an issue in this litigation. (SAC §§ 71-77/1.CT.90-92; SAC §§ 194-199, Footnote 72/1.CT.123-124)

But, physicians and institutions have, from time to time, attempted to claim "off-label" application of a test device in order to evade the FDA's IDE requirements. In the following warning letters, the FDA distinguishes "investigation" from "treatment." In a 3 April 2007 FDA warning letter to Thomas P. Davis, M.D., St. John Hospital and Medical Center, regarding an

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attempt to characterize his device investigations as an "off-label" application, the FDA states, at page 2:

> Pursuant to 21 CFR 812.20(a)(1) and 812.20 (a)(2), a sponsor shall submit an application to the FDA if the sponsor intends to use a significant risk device as defined by 21 CFR 812.3. Furthermore, a sponsor shall not begin an investigation for which an IDE is needed, until FDA has approved the application.

The letter goes on:

> Your written response states that you were

> not aware that an IDE was required for an FDA-approved [redacted] to be used off-label, that there was no assessment of degree o risk from the IRB, and that you were not aware that you met the definition of a sponsor-investigator. Your response also states that when it was discovered that an IDE was required, one was submitted. We note that the IDE that you submitted requested retrospective approval, and you have been notified that your request was not approved.

In the publication, *FDA IRB SR/NSR Guidance*, supra, at "question 55," the FDA states:

> Does a clinical investigation involving a marketed product require IRB review and approval?
>
> Yes, if the investigation is governed by FDA regulations [see 21 CFR 56.101, 56.102(c), 312.2(b)(1), 361.1, 601.2, and 812.2].

(See also the FDA publication: Off-Label and Investigational Use Of Marketed Drugs, Biologics, and Medical Devices.)

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Lastly, Respondent Researches involved Nadine in

a course of medical research, *not* medical treatment. They said so. (SAC §§ 163-176/1.CT.128-131; See also *Off-label Prescribing* at page 319, 329, *infra*.)

8. "Standard of care" no excuse for not obtaining IDE

In a 3 October 2006 FDA warning letter to Steven J. Morgan, M.D. [OnDisc] (P. 1-2), the FDA states:

> In your response you state that you were using the [redacted] as the "standard of care" and that your intent was to give your patients the best possible care. Use of a legally marketed device for an indication that has not been FDA-approved or cleared is permissible within the context of a legitimate health care practitioner-patient relationship.
>
> A physician that conducts an investigation, which is defined as a clinical investigation or research involving one or more subjects to determine the safety or effectiveness of a device, 21 CFR 812.3(h), with a device for an indication that has not been FDA-approved or cleared must obtain an FDA-approved investigational device exemption (IDE) [21 USC 360j(g), 21 CFR Part 812] ... This clinical investigation of the safety and effectiveness of a new indication for the [redacted] requires an FDA-approved IDE.

You failed to obtain approval of an IDE prior to the conduct of this investigation.

This situation parallels Respondent Researchers use of the temperature probe at issue in this case. They could not legally employ the device as envisioned without first obtaining an IDE from the FDA (and all that process requires, including Nadine's informed consent). (SAC §§ 69-88/1.CT.90-95; SAC §§ 155-218/1.CT.113-129; 4.CT.898-899, 903-904; 1035-1036, 1039-1040)

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## VI. REGENTS' HUMAN SUBJECT RESEARCH INDISCRETIONS

Just a hand-full of warning letters sent to the University of California by DHHS and FDA is all that is necessary to demonstrate a "less than attentive," if not disdainful attitude on the part of UC researchers toward obtaining required approval and consent for their human subject research. These communications show that the Regents have actual knowledge that, over a period which extends from before Nadine's procedure to the present, patients are being endangered and killed by unlawful medical research experimentation.

The relevance of these documents to the instant case is that they show that in the circumstances of this case, IRB review and approval, as well as Nadine's informed consent is a minimum requirement for beginning the kind of human subject research to which she was surreptitiously exposed. Add to this the FDA IDE

requirements associated with application of an approved device to a new use, and it becomes clear that such conduct as Nadine was subjected to (SAC § 78/1.CT.92), was unlawful and that there was no consent to it, actual or implied. (See *New Intended Uses Require an IDE from the FDA*, at page 293; *Judicial Notice of Civil Code § 3513 Issues*, at page 282)

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### A. Attorney General Declares the PHSMEA Will Not Be Enforced?

Respondent Regents have determined that adherence to Health & Safety Code § 24170, et. seq. (Protection of Human Subjects in Medical Experimentation Act or PHSMEA) is a mandatory obligation for all University of California investigators. (SAC §§89-90/1.CT.95-96; 1.CT.167-169). But, in the letter dated 20 December 1996, on page 2, Joanna Beam, University Counsel, states:

> The California Department of Health Services and the California Office of the Attorney General are charged with enforcement of the provisions of the Act. Rumors have circulated that these departments have not and do not intend to enforce the provisions of the Act. (1.CT.168)

In this context then, the following hyperlinked documents

are described. (See also The Legacy of the Tuskegee Syphilis Study published by the Association of Schools of Public Health as part of their on-line Ethics and Public Health: Model Curriculum.)

### B. Deaths at University of California at San Francisco (UCSF)

Decedent Nadine Secarea is not the first patient Respondent Regents' researchers have killed in surreptitious/unapproved medical experimentation. In unauthorized device experimentation performed at the University of California at San Francisco (UCSF), at least 5 deaths were associated with investigational device studies. (FDA Warning letter, below, at pp. 5-6, 7-8).

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An FDA warning letter dated 25 March 2004, to Timothy A. M. Chuter, M.D., at the University of California at San Francisco [OnDisk], describes numerous violations of federal regulations involved in medical device investigations, including failure to adhere to the stated protocol associated with the FDA-issued IDE (p. 2), failure to obtain informed consent (pp. 4-5) and attempts to conceal medical research under a guise of "emergency" and "compassionate" use (p. 6).

In addition, there was evidence that records were "manipulated." As the FDA observed, on page 4:

> A discharge evaluation form demonstrates

> that Subject [...] (IDE [...]) had a falling hematocrit and was given two units of packed red blood cells, but this information was crossed out and "error" was-written above it. However, the dictated hospital discharge summary states that this subject did have a falling hematocrit and was given two units of packed red blood cells.

On page 5, top, the FDA enumerates many discrepancies regarding informed consent. For one, if the dates of the patient and witness do not agree, it appears the informed consent signing was not actually "witnessed." In addition, signed informed consents could not be "located."

Again on page 5 (bottom):

> The injury was reported to CHR on December 20, 2002, [...] You sent a letter dated November 15, 2002, to FDA informing of this death, although this date was prior to the subject's death.

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Indeed, Respondent Researchers have used this device in this very litigation. (See *Only UCLA respondents know the whole truth*:AOB:11-12)

Moreover, this kind of "records manipulation" suggests a callousness to the legal requirements of human

experimentation that appears to extend across the University's medical enterprise (at least according to my review of warning letters, not all of which are included in this motion)..

In a 25 July 2003 DHHS OHRP warning letter to Regis Kelly, Ph.D., Executive Vice Chancellor, University of California, San Francisco [OnDisc], significant deviations from informed consent requirements were described, and, at page 9, there appears to be an admission that research was masquerading as "standard of care:"

> Regarding '*Both types of [fluid management] methods are considered standard of care*', we agree that this phrase is suboptimall. While the specific interventions in the management strategies are considered standard of care, the actual strategies themselves are experimental.

Appellant asserts that this tactic is precisely what Respondent Regents and Respondent Researchers are attempting to do in this litigation. (See Respondent Researchers' ACC 2005-Presentation Abstract [OnDisc], JACC 2005 Scientific Session Review [OnDisc] at page 32B.) Thus, it is imperative that the character of their actions, not the "labels" they place upon them, are carefully scrutinized.

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In a 13 January 2003 DHHS OHRP warning letter

to Regis Kelly, Ph.D., Vice Chancellor for Research, University of California, San Francisco [OnDisc], it was revealed that two patients were killed in a "prospective, non-exempt research [study that] was conducted without review or approval by the UCSF IRB, as required by DHHS regulations at 45 CFR 46.109, and without obtaining the legally effective informed consent of the subjects, as required by DHHS regulations at 45 CFR 46.116."

In an 8 February 2002 DHHS OHRP warning letter to Zach W. Hall, Ph.D., Executive Vice Chancellor, University of California, San Francisco [OnDisc] (p. 2), it was revealed that in one study, 36 of 43 subjects were unable to provide legally effective informed consent and in another, 53 of 62 could not. Instead, "consent" was obtained from sometimes questionable "surrogates."

In a 27 August 2001 DHHS OHRP warning letter to Zach W. Hall, Ph.D., Executive Vice Chancellor, University of California, San Francisco [OnDisc], the University was found to be engaging in human experimentation without obtaining IRB approval or the subject's informed consent.

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### C. FWA Denial at University of California at Berkeley (UCB)

Apparently, UCB will tolerate no oversight of their human subject experimentation. In a 33 page 29 June 2007 DHHS OHRP warning letter to Mary B. Burnside, Vice Chancellor for Research, University of California at

Berkeley [OnDisc], the University was found to have woefully inadequate procedures for conducting human subject experimentation. In response, the University simply denied responsibility under its Federal-Wide Assurance (p. 2) for adhering to DHHS requirements, to wit:

> OHRP acknowledges UC Berkeley's statement that "we do not specify in our federal wide assurance that we will apply 45 CFR 46, or its subparts, to research that is funded by non-federal monies." OHRP notes, however, that UC Berkeley voluntarily extended its Multiple Project Assurance (MPA)/FWA to all research, regardless of funding source, until July 2004; at which time UC Berkeley decided to limit the applicability of its FWA to research conducted or supported by the Department of Health and Human Services (HHS) or by any other federal department or agency that has adopted the Federal Policy for the Protection of Human Subjects, known as the Common Rule. Given these facts, OHRP has jurisdiction over all institutional review board (IRB) activities relating to non-exempt human subject research that occurred prior to July 2004, regardless of funding source. In addition, OHRP has jurisdiction over all IRB activities relating to non-exempt human subject research that: (1) occurred after July 2004; and (2) is conducted or supported by

HHS. As a result, the findings, questions and concerns listed below only relate to IRB activities for which OHRP has jurisdiction.

Indeed UCB, in the University of California Berkeley, Human Research Protection Program Policies and Procedures application for

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University of California at Berleley, Federalwide Assurance (FWA) for the Protection of Human Subjects, at page 186, expressly states that it will *not* apply the Common Rule (45 CFR 46) to non-DHHS funded research. That, notwithstanding the Regents have decreed that the Common Rule will be applied to all research. See the University of California Contract & Grant Manual, chapter 18, section 18-220, Applicability of Governmental Regulations and Policies to All Research. (1.CT.97-102)

The inescapable conclusion is that UCB has, as a practical matter, made itself unaccountable to following that rule, and shrouded much of its human subject research enterprise in secrecy, as it seems the Respondent Regents do not "self-police." But, it is noteworthy that UCB is not alone in that respect. Eastern Virginia Medical School did likewise in 2005.[3] (See page 2, bottom, 15 June 2006 DHHS OHRP warning letter to Robert Williams, Ph.D., Associate Dean for Research Subjects Protection, Eastern

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[3] Note that no attempt was made to ascertain how many institutions represented in the published on-line DHS OHRP warning letters might be following this course of action.

Virginia Medical School [OnDisc].)

The import of these actions by Respondent Regents, whether at UCB or elsewhere in the UC system, is that they show an aversion to adhering to regulations regarding human subject medical research. As will

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be shown next, Respondent Regents at UCLA and Respondent Researchers show a similar disinclination to "telling the truth" as well as to adhering to human subject experimentation regulation. (See also Publication of "Less Than Entirely True"Research Results" SAC §§ 203-211/1.CT.125-127)

### D. Surreptitious Medical Experimentation at UCLA

Unlike UCB, the UCLA (FWA) Assurance Policies (discussed infra) provides that all requirements of 45 CFR 46 will be met for all human subject research regardless of sponsorship. That's the promise. The reality is somewhat different.

#### 1. UCLA's less than diligent efforts to conform to the law

In an 8 page 14 February 2006 DHHS OHRP warning letter to Roberto Peccei, Ph.D., Vice Chancellor for Research, University of California at Los Angeles [OnDisc], DHHS OHRP, describes, at pages 2-3, human subject research conducted on unsuspecting patients (like Nadine),

to wit:

> (b) Research reported in the abstract: Transient Post-Operative Hypotony Following Transconjunctival 25 Gauge Vitrectomy. A. Gupta, C.R. Gonzales, S.Y. Lee, J.Y. Freeman, M.F. Estafanous, A.E. Kreiger and S.D. Schwartz. Invest Ophthalmol Vis Sci 2003;44: E-Abstract 2026.
>
> Your November 10, 2005 report states that "...1) the abstract was presented and published prior to the retrospective study IRB #04-07-004-01 approval by the IRB on August 17, 2004, and 2) the application to the IRB for the prospective study IRB #01-11-057-01 describes that only 23 eyes at UCLA

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would be evaluated (of the 93 total for the multicenter study) and the abstract reports that '100 consecutive eyes' were evaluated. The explanation provided by Dr. Schwartz regarding the discrepancy in the number of eyes indicates that the data obtained from the additional eyes was through the routine care of patients not obtained under the approved research project. **Therefore, the above-referenced abstract describes research that was not reviewed and approved by the UCLA IRB.**

[emphasis in original]

And, there are more of allegations of this character in this document.

In a 19 March 2002 DHHS OHRP warning letter to Wyatt R. Hume, D.D.S., Ph.D., Executive Vice Chancellor, University of California at Los Angeles [OnLine], DHHS OHRP, after "reminding" UCLA investigators, at page 2, that "Department of Health and Human Services (HHS) regulations at 45 CFR 46.116 and 46.117 stipulate that no investigator may involve a human subject in research unless the investigator has obtained and documented the legally effective informed consent of the subject," they offered the following additional guidance, at page 3:

> HHS regulations at 45 CFR 46.111(a)(6) require that in order to approve research covered by the regulations, the IRB shall determine, when appropriate, that the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects [...] specifically, that the subjects will be monitored weekly via clinical evaluation by the investigator to assess potential adverse effects.

This raises a question as to why Drs. Swerdlow and Shivkumar made no effort to closely monitor the patients they experimented on, including Nadine, to ascertain whether or not they were suffering adverse effects of

the experimentation they were subjected to. Given the facts of this case, it appears Respondent Researchers had no plan to come to the aid of any of these patients under any circumstance, as evidenced by their failure to come to the aid of Nadine.

In a 24 October 2001 DHHS OHRP warning letter to Wyatt R. Hume, D.D.S., Ph.D., Executive Vice Chancellor, University of California at Los Angeles [OnDisk], DHHS OHRP, describes, at page 2, a memorandum regarding human subject experimentation at UCLA. It states:

> In June 2000, you distributed a memorandum to all UCLA faculty, students, and staff stating that "no UCLA faculty, staff, or students may conduct human subject research without obtaining prospective IRB approval or a certified Claim of Exemption from IRB review.

In addition, DHHS OHRP provides significant guidance on pages 2-3, as to what is expected of UCLA to fulfill their legal obligations, under the circumstances of the warning letter.

But, it is clear that Respondent Regents (at UCLA) had no intention of enforcing the policy enunciated in the June 2000 memorandum, because as can be seen, Nadine and other patients have been subjected to surreptitious

human subject experimentation since that time, apparently, with impunity. And, what was Respondent Regents reaction when they are called to task for these acts? They claim government immunity. (AOB:42)

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But, seen from a "causation" perspective, if Respondent Regents (at UCLA) had kept the promise they made in the June 2000 memorandum, the covert medical experiment to which Nadine was subjected would not have occurred, there would have been no ablation line across her left posterior wall to accommodate the experimentation at issue in this case (SAC § 213/1.CT.127), Nadine would not have suffered the atrio-esophageal fistula (with no left posterior wall ablation line to "place" the fistula, there's no fistula), and this litigation would not be taking place. (4.CT.946, 1082)

### 2. Drs. Swerdlow and Shivkumar knew their legal obligations

Drs. Swerdlow and Shivkumar knew of their legal obligations regarding IRB approval and subject informed consent, before engaging in device experimentation. In their 2003 publication: Charles Swerdlow, MD; Kalyanam Shivkumar, MD, PhD; Jianxin Zhang, MS, Determination of the Upper Limit of Vulnerability Using Implantable Cardioverter-Defibrillator Electrograms, *Circulation*. 2003;107:3028-3033 [OnDisk], at page 3028, they acknowledge:

> Patients were candidates for this study if they had left pectoral implants of an ICD with a lead implanted at or near the right ventricular apex. **All gave written, informed consent according to a protocol approved by the Human Subjects Committee**. [Bolding added]

Respondent Regents and Respondent Researchers may not now deny they had actual knowledge of their duty to procure informed consent

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and IRB ("Human Subjects Committee") approval before undertaking the human subject device-related experimentation which is at issue in this case.

## VII. DOCUMENTS FROM UCOP

The following documents, some already referenced, are published by the University of California Office of the President (UCOP).

The University of California Contract & Grant Manual, chapter 18, section 18-220, Applicability of Governmental Regulations and Policies to All Research. [OnDisk] (1.CT.97-102) establishes that the Federal rules for human subject experimentation apply to all UC human subject studies, "regardless of the source of funding or whether the research is funded." (45 CFR 46, the Common Rule; 21 CFR 50, 21 CFR 56, for new drugs, 21 USC 355(i); for

devices 21 USC 360(g)). (See 1.CT.84, 85, 97-103; AOB:34)

## VIII. DOCUMENTS FROM UCLA OPRS

UCLA Office for Protection of Research Subjects (OPRS) is, according to this Web Page, the organization primarily responsible for implementing the policies established by Respondent Regents, at UCLA.

And, the UCLA OPRS home page plainly states that "Please Note: No UCLA Faculty, staff, or students may conduct human subject research

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without prospectively obtaining IRB approval or a certified Claim of Exemption from IRB review."

However, the human subject experimentation to which Nadine (and other patients) were subjected was NOT approved by any IRB (or HSPC, as UCLA also refers to these committees).

### A. OPRS Policies

The UCLA OPRS Policies & Guidance page provides a listing of regulations applicable at UCLA. Of particular interest is the UCLA Federalwide Assurance (UCLA Assurance Policies) and the Investigator's Manuals.

### B. UCLA FWA and SOPs

Unlike UCB FWA, UCLA's FWA Assurance

Policies[4] [OnDisc] provides that:

> All requirements of Title 45, Part 46, of the Code of Federal Regulations (45 CFR 46) will be met for all applicable DHHS-supported research, and all other human subject research regardless of sponsorship, except as otherwise noted in this Assurance.

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In addition, UCLA OPRS, in the University of California, Los Angeles Office for Protection of Research Subjects Standard Operating Procedures (SOPs), at page 254, Policy Number 45, defines:

> Assurance: A contract or agreement that establishes standards for human subjects research as approved by the Office for Human Research Protections (OHRP).

If an Assurance is a contract, it is a contract made to benefit and to protect third parties from surreptitious and covert human subject experiments. In the instant case, the UCLA (FWA) Assurance Policies [OnDisc] agreement with DHHS OHRP, was intended to protect Nadine from

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[4] The UCLA (FWA) Assurance Policies document is "hidden" and cannot be directly accessed from any OPRS page (as of this writing). The document URL must be known in advance. (http://oprs.ucla.edu/human/documents/pdf/UCLA-Assurance-Policies.pdf)

the actions of Respondent Researchers. But, as can be seen from the DHHS OHRP warning letters, it is apparently a promise Respondent Regents (at UCLA) had no intention of keeping. (See *Surreptitious Medical Experimentation at UCLA*, at page 309.)

### C. Investigator's Manual for t he Protection of Human Subjects

The (UCLA (FWA) Assurance Policies [OnDisc]) has been discussed previously, but it is the Investigator's Manual that contains a detailed summary of the legal obligations for human subject research. (SAC §§75-76/1.CT.91-92; SAC §§ 98-108/1.CT.103-105)

There are two versions of this document currently on-line. Ths first is the current (2006) revision. It will be referred to a UCLA 2006 Investigator's Manual for the Protection of Human Subjects [OnDisc]. However, the version that was current at the time if Nadine's ablation procedure was the 1997 revision: UCLA 1997 Investigator's Manual for the Protection of Human Subjects [OnDisc].[5]

The PDF document, just described does not contain referred-to appendices. The entire manual, including appendices is: UCLA 1997 Investigator's Manual

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[5] This version of the Investigator's Manual for the Protection of Human Subjects is "hidden" and cannot be directly accessed from any OPRS page (as of this writing). The URL must be known in advance.
(http://www.oprs.ucla.edu/human/manual/hspcmanual/hspc497c.pdf)

for the Protection of Human Subjects (All).[6] This web-based manual is a combination of HTML and PDF files, but contains the complete document. For some unknown reason, UCLA 2006 Investigator's Manual for the Protection of Human Subjects does not provide the appendices listed beginning on page vii.

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However, these sections are found in the UCLA 1997 Investigator's Manual for the Protection of Human Subjects (All) document.

### D. Patient Rights: 22 CCR 70707

Respondent Regents are obligated to conform to California Code of Regulations, Title 22 §70707 Patient Rights, in their operation of UCLA Medical Center, which provides, among other things that a patient has the

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right to "be advised if hospital/personal physician proposes to engage in or perform human experimentation affecting care or treatment. The patient has the right to refuse to participate in such research projects." And, the right to "[...]

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[6] This version pf the full HTML-PDF Investigator's Manual for the Protection of Human Subjects is "hidden" and cannot be directly accessed from any OPRS page (as of this writing). The URL must be known in advance. (http://www.oprs.ucla.edu/human/manual/TOC)

know the name of the person who will carry out the procedure or treatment." (AOB:31)

## IX. OFF-LABEL PRESCRIBING

Off-label: Referring to the use of a drug for a condition or disorder not listed in the official FDA labeling. (Gale Encyclopedia of Medicine.) Whether the Vital Signs probe at issue in this case could have been used "off-label" is an issue in this case. It was not raised by Respondent Regents nor by Respondent Researchers in their Motions for Summary Judgment, but is an issue in the Second Amended Complaint. (SAC §§ 71-74/1.CT.90-91; SAC §§ 194-199, Footnote 72/1.CT.123-124) The relevance to this case is that Respondent Researchers had no knowledge about the principles of operation of this device, such as to justify its use outside the parameters of its intended application. (SAC §§ 192-197/1.CT.122-124)

### A. Off-Label the FDA View

In its advice page, Off-Label and Investigational Use Of Marketed Drugs, Biologics, and Medical Devices, the FDA states:

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> If physicians use a product for an indication not in the approved labeling, they have the responsibility to be well informed about the product, to base its use on firm scientific rationale and on sound medical evidence, and

to maintain records of the product's use and effects.

### B. Off-label: Respondent Regents View

According to the UCLA 1997 Investigator's Manual for the Protection of Human Subjects [OnDisc], at page 9-7:

> ***"Off-Label" (Unapproved) Use in Medical Practice***
>
> FDA permits the "off-label" use of an ***approved*** product (for a purpose or at a dosage different from approved uses) in the course of professional practice—*i.e.*, for care of individual patients. **When it occurs with the intention of contributing to generalizable knowledge, however, or the physician contemplates reporting the results—even as a collection or series of case studies—the activity is viewed as research and thus is subject to prior HSPC review and approval.** [Bold in original.]

But, the use of this probe was part of a human subject medical device study. Consequently, according to Respondent Regent's (at UCLA) own rules and regulations, the use of the Vital Signs probe at issue in this case could not be used in Nadine's surgery without "prior HSPC review

and approval," notwithstanding any other consideration. (See Respondent Researchers' ACC 2005-Presentation Abstract [OnDisc], JACC 2005 Scientific Session Review [OnDisc] at page 32B; see also UCLA 2006 Investigator's Manual for the Protection of Human Subjects [OnDisc] at page 9-7 for the identical requirement, but now emphasized in bold type.)

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## C. Off-label: the Medical Community View

The medical community has recognized that off-label prescribing caries risks of which patients should be made aware. The Mayo Clinic, provides the following advice in its on-line information for patients: Off-label drugs and medical devices: Get the facts.

In this document, patients are advised:

> **Any concerns with off-label use of drugs or medical devices?**
>
> While off-label use of drugs or medical devices is relatively common, some experts have raised concerns. These include:
>
> - Lack of evidence. While there is reliable information that some drugs are effective when used off-label, for others there is little to no evidence of effectiveness. As a result, the FDA and others are concerned

that some off-label use might be ineffective or even dangerous. While the FDA doesn't prevent off-label use, it doesn't promote off-label use, either.

- Reimbursement. Some insurance companies won't cover the cost of a drug — most often if it's a costly drug — if it's prescribed for off-label use. Depending on your state's laws, insurers could be required to cover care that is "medically appropriate." If your doctor can prove — through the use of peer-reviewed medical studies or other reliable information — that off-label is appropriate, that should help bolster your case in getting reimbursement.

**Questions about off-label use for your doctor**

It's helpful to have a conversation with your doctor about off-label use and its appropriateness. Some questions you'll want to ask include:

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- Is there any evidence the drug you're suggesting be used off-label is effective? What is that evidence, and how reliable is

it? Ask for references or information supporting the off-label use.

- Is the off-label use of this drug likely to work better than the standard or approved treatment?

- What are the potential side effects and other risks associated with this drug if I use it off-label? [Color emphasis added.]

But, here seems to be one shortcoming in this advice so far as Californians are concerned. In the section "Questions about off-label use for your doctor," *it would seem that this is information a physician is required to disclose, rather than being the patient's responsibility to inquire*. ("First, a physician must disclose to the patient the potential of death, serious harm, and other complications associated with a proposed procedure. [Citation.]" Wilson v. Merritt (2006)142 Cal.App.4th 1125, 1134, quoting Daum v. SpineCare Medical Group, Inc. (1997) 52 Cal.App.4th 1285, 1301-1302.) "Second, '[b]eyond the foregoing minimal disclosure, a doctor must also reveal to his patient such additional information as a skilled practitioner of good standing would provide under similar circumstances.' [Citation.]" (Id. at p. 1302.)

In the eMJA (The Medical Journal of Australia) an article entitled Off-label use of medicines: consensus recommendations for evaluating appropriateness [OnDisc]

describes an approach for systematically evaluating the appropriateness of medicines proposed for off-label use.

In particular, the authors emphasize that:

- Three broad categories of appropriate off-label use are identified:
  - off-label use justified by high-quality evidence;
  - use within the context of a formal research proposal; and
  - exceptional use, justified by individual clinical circumstances.
- An appropriate process for informed consent is proposed for each category.
- If there is no high-quality evidence supporting off-label use, and the medicine is not suitable for exceptional or research indications, its use is generally not recommended. This will reduce inappropriate use, enhance patient safety by reducing exposure to unnecessary risk, and may stimulate more clinically relevant medicines research.

The two components of ths consensus most important to patients is known effectiveness and informed consent. And, this theme is consistent with the advice given by the Mayo Clinic.

Finally, in a continuing education article entitled What are the Legal Issues Regarding the Use of Off-label Drugs? published *Retina Today*, the author advises in this mini-lesson for ophthalmologists:

> If physicians use a product off label, they have a responsibility to be well informed about the product ... use

**[RFJN Original: Page 47]**

> firm scientific rationale and sound medical evidence." (Page 44)

The author warns:

> The use of off-label drugs combined with an adverse outcome is a potential malpractice disaster. A disaster that is akin to blood in the water for lawyers.
>
> The key to managing this risk—and it can only be managed not eliminated—is informed consent. Informed consent is a process, not a form. Within the off-label context, we must discuss with patients the

off-label status of the proposed therapy and potential risks. We should consider using a drug-specific consent form, and very importantly, we must document why and how the decision was made to not use FDA or Centers for Medicare and Medicaid Services (CMS) approved therapies." (p. 44-45)

The consistent theme in the advice drom the medical community is that efective use of off-label therapies includes knowledgeable application and informed consent.

## D. Off-label: Medical Insurance Community View

Insurers have become involved in off-label prescribing as some will not reimburse such expenses as being "experimental." Thus, the issues surrounding off-label use affects every potential patient.

Not all insurers publish their off-label reimbursement requirements on-line, but Health Plan of New York does, and its guidelines for Off-Label Use of FDA-Approved Drugs [OnDisk] are quite broad and at the very least, require (at page 2):

**[RFJN Original: Page 48]**

A use that is an accepted standard of medical practice. 'Are there published recommendations from specialty societies or in other authoritative evidence-based

guidelines' (e.g., a state-of-the art review article published in a recognized textbook or a reputable publication).

*Note: Acceptance by individual health care practitioners, or even a limited group of health care practitioners, does not typically indicate general acceptance by the medical community. Testimonials indicating such limited acceptance and limited case studies, distributed by sponsors with potential financial conflict of interest in the outcome, are not sufficient evidence of general acceptance by the medical community.* [Italics original.]

In other words, if patient "treatment"is the intent, then something more than speculation about the safety and efficacy of an "off-label" application is needed to demonstrate that fact.

### E. Off-label: the Scientific Community View

In their publication, Y. David, W. A. Hyman, Issues Associated with Off Label Use of Medical Devices, [PaperOnDisk] Proceedings of the 29th Annual International Conference of the IEEE EMBS, Cité Internationale, Lyon, France August 23-26, 2007.

The authors present guidelines for informed off-label device use. They conclude that that application of devices "off-label," without knowledge of device limitations,

or without adequate analysis of suitability for the intended use, or without evaluating when another device may be more appropriate and labeled for the desired application, is not acceptable. (p. 3558).

**[RFJN Original: Page 49]**

Had Respondent Researchers given a proper consideration to the capabilities of the Vital Signs probe at issue in this case, the medical experimentation in which they engaged would not have taken place, because Respondent Researchers would have quickly learned that they could not provide a sound scientific basis to justify the proposed use of the probe either to the UCLA IRB or to the FDA in pursuit of an IDE, much less in an "off-label" application of this device as they envisioned it.

**F. Off-label: A Question for this Court**

The question of disclosure regarding off-label use of FDA-approved devices is an issue in this case. Appellant asks this court to decide it. What is a physician, as a matter of California law, required to disclose to a patient before engaging in off-label use or prescribing? But, the real question is: can patients in California be "kept in the dark" about their physicians' off-label use of drugs and/or devices in their treatment and care? This question is prompted by the Mayo Clinic's advice, *supra*. If a patient doesn't know about the contemplated off-label use in the first instance, the inquiry the Mayo Clinic suggests can never take place. If the questions the Mayo Clinic suggests are important

enough to ask, then a patient at least needs to be put on notice to make the inquiry.

**[RFJN Original: Page 50]**

## X. MEDICAL RESEARCH OR MEDICAL PRACTICE?

Respondent Researchers' announced the results of their medical device research are at the American College of Cardiologists (ACC) Annual Scientific Session in March, 2005. There can be no dispute that their effort was intended contribute to generalizable knowledge. They said so. (Respondent Researchers' ACC 2005-Presentation Abstract [OnDisc]; JACC 2005 Scientific Session Review [OnDisc])

But, what are the responsibilities of researchers? What is their relationship to the human subject? Is medical research a "practice of medicine?" Or, are these concepts so disparate that the one in no way relates to the other.

The Second Amended Complaint alleges that Respondent Regents and Respondent Researchers violated California Health and Safety Code § 24170, et. seq. (SAC §§ 89-92/1.CT.95-97) Thus, it is an issue in this case.

The question of what is a medical experiment can be a close one. The Respondent Researchers in this case explained to this Appellant that what they did to his wife, decedent Nadine Secarea (without her knowledge or consent), was a medical experiment. Now after publishing their work, and its being acknowledged as research, they ask this court to "say it isn't so." (SAC §§ 155-218/1.CT.113-129; 4.CT.898-899, 903-904; 1035-1036, 1039-1040;

Respondent Researchers' ACC 2005-Presentation Abstract [OnDisc] JACC 2005 Scientific Session Review [OnDisc] at page 32B.)

A law review by E. Haavi Morreim, Medical Research Litigation And Malpractice Tort Doctrines: Courts on a Learning Curve [OnDisk], 4 Hous. J. Health L & Pol'y (2003), goes a long way toward answering the question: "what is research?"

First, the author points out, at page 17:

> If the activity is designed "'to test an hypothesis, permit conclusions to be drawn,' and thereby to develop or contribute to generalizable knowledge, it is research." [Footnote]

And at page 18-19:

> "[...] it is not the goal of any re-search protocol to benefit any specified individual. Rather, it is to learn information. Benefit to any given individual is thus by good fortune, not by design, even if it happens that many individuals in that study benefit.

Then, at page 20, the author contrasts "research" with "treatment":

> A research protocol is not treatment, no

> matter how much all parties wish it so. Treatment requires genuine attention to the best interests of the patient as an individual, including individual attention and individual tailoring or complete changing of any regimen for maximal efficacy. Even if the organization, scope, and duration of a clinical trial were compatible with these goals, the uncertainties and unknowns attendant upon use of an unproven intervention make individual tailoring almost meaningless, especially in early-phase trials. Moreover, the trialists' mandate to collect data systematically makes individual tailoring largely incompatible with the development of generalizable knowledge.

**[RFJN Original: Page 52]**

At page 26, the distinction relevant to this case, is made:

> [...] the bare fact that a physician has performed an intervention, or that it required some professional knowledge or skill, does not mean that intervention was medical practice.

Some examples:

In *Barrett v. United States* (2nd Cir. 1982) 689 F.2d 324, 329, a psychiatric patient died after being given experimental mescaline without his knowledge or consent.

The court held that "[t]he gravamen of the FTCA claim is that the real reason Blauer died was not medical incompetence, but the fact that he was used as a human guinea pig."

In *In Re Cincinnati Radiation Litig.* (S.D. Ohio 1995) 874 F. Supp. 796, 800, 814,.the court found that, when scientists exposed cancer patients to total body irradiation as part of an undisclosed military study, the researchers "were not acting as physicians when they conducted experiments on unwitting subjects at Cincinnati General Hospital. . . Rather, the defendants were acting as scientists interested in nothing more than assembling cold data [...]"

In *Anderson v. George H. Lanier Memorial Hosp.* (11th Cir. 1993) 982 F. 2d 1513, 1519, where patients unknowingly received an experimental intraocular lens (IOL) implant the court held that "their claim is that they were never put on notice that they were the subjects of research. . . . Under the ruse of removing cataracts, Dr. Torsch may have committed

**[RFJN Original: Page 53]**

fraud on these appellants when he inserted experimental IOLs in their eyes."

In *Kus v. Sherman Hospital* (Ill. App. Ct. 1995) 644 N.E.2d 1214, 1220, a physician-investigator, after his study was approved by the Institutional Review Board (IRB), altered the approved consent form to describe the experimental implant as routine and well-accepted. The Illinois appellate court held that "[c]learly, the medical

battery claim is warranted under existing law." Id. at 1220.

In an unusual twist, subjects in a discontinued cancer study sued to be enrolled in a new study. In *Spenceley v. M.D. Anderson Cancer Ctr.* (S.D. Tex. 1996) 938 F. Supp. 398, 398, the court denied their claim and observed:

> Research is not treatment. Experiments require measurements and conditions that may not be therapeutically significant. The disappointment of patient-participants is not the result of a wrong inflicted on them; they are frustrated in not receiving a potential cure, but they were permitted to have the drug for the purpose of research—the [M.D. Anderson Cancer Center's] purpose not theirs. They were the incidental, gratuitous beneficiaries of the research. . . . Research is not standard; it is speculation, approximation, and inquiry.

This statement of affairs is directly relevant to this litigation, as Nadine was subjected to not medical treatment, but medical research. Put another way, research is not medical treatment and medical treatment is not research.

The author collects these thoughts at page 64:

**[RFJN Original: Page 54]**

> While medical practice seeks to

> benefit the individual patient, research seeks generalizable scientific knowledge via activities in accordance with a protocol. Therefore, when patients are subjected to research without their knowledge or consent, the investigator has covertly made a profound
> change of goals. Whereas the patient believes his personal welfare is the primary goal, the real goal is now to benefit society by following the protocol, even sometimes contrary to the patient's best interest.
>
> At the same time, the physician has also shifted his relationship with the patient from a fiduciary physician- patient relationship to a nonfiduciary investigator-subject connection.

Referring back to page 18, *footnote* 94, in Jay Katz, Human Experimentation and Human Rights, 38 St. Louis U. L.J. 7, 14-15, 34 (1993):

> [I]n therapeutic encounters, unlike research encounters, physicians are expected to attend solely to the welfare of the individual patient before them. . .in clinical research, on the other hand, patient-subjects are also being used for the ends of science.

Then at note 94, at page 25, of his article, Katz writes:

> Respect for the subjects' human rights dictates that they know that the decision to participate in research entails making a gift for the sake of others.

Nadine went to Drs. Swerdlow and Shivkumar for medical treatment. She didn't engage their services to make "a gift for the sake of others," includes the training of Dr. Cesario. (See SAC §§ 219-221/1.CT.129-130)

**[RFJN Original: Page 55]**

Lastly, Appellant believes that this review is so well researched and conceived, it could serve as the legal framework for deciding this case, given that it addresses issues of consent, ghost surgery and medical experimentation.

## XI. SCIENTIFIC DOCUMENTS

A. Publications Referenced in the Second Amended Complaint

Gillinov A, Pettersson, Rice T. "Esophageal injury during radiofrequency ablation for atrial fibrillation," *J Thorac Cardiovasc Surg.* 2001; 122: 1239-1240 [FullPaperOnDisc] (1.CT.115)

Pappone C, et. al., Atrio-esophageal fistula as a complication of percutaneous transcatheter ablation of atrial fibrillation. *Circulation.* 2004;109: 2724–2726. [FullPaperOnDisc] (1.CT.115, 128, 129)

Cesario, D., et. al., Esophageal Temperature Monitoring During Left Atrial Catheter Ablation for Atrial Fibrillation, *J Am Coll Cardiol.* 2005 Feb 1;45(4):114A-115A (Abstract). (903-904; 1039-1040)

Redfearn DP, et. al., Esophageal temperature monitoring during radiofrequency ablation of atrial fibrillation. *J Cardiovasc Electrophysiol*. 2005 Jun; 16(6): 589-93. [FullPaperOnDisc] [At page 592, the authors state that "The mechanism of injury to the esophagus during left-atrial ablation has not been defined . . ."] (1.CT.120)

**[RFJN Original: Page 56]**

Doll N, et. al., Esophageal perforation during left atrial radiofrequency ablation: is the risk too high? *J Thorac Cardiovasc Surg*. 2003;125:836–842. [FullPaperOnDisk] [At page 840, the authors report that "[a]lthough the number of patients with esophageal perforation in the current study was small, it is troubling that we were unable to identify any reliable predictors of this life-threatening injury."] (1.CT.120, 128)

Benussi S, et. al., A Tailored Anatomical Approach to Prevent Complications During Left Atrial Ablation. *Ann Thorac Surg*. 2003 Jun;75(6):1979-8 [FullPaperOnDisk] (1.CT.128)

Sonmez B, et. al., A fatal complication due to radiofrequency ablation for atrial fibrillation: atrio-esophageal fistula. *Ann Thorac Surg*. 2003;76:281–283. [FullPaperOnDisc] (1.CT.128)

## B. Publications Referenced in Appellant's Reply Brief

Cummings JE, et. al., Brief communication, Atrial-esophageal fistulas after radiofrequency ablation. *Ann Intern Med* 2006;144:572-574 [FullPaperOnDisk] (ARB:30)

Cummings, J.E., et. al., Esophageal Luminal Temperature Measurement Underestimates Esophageal Tissue Temperature During Radiofrequency Ablation Within the Canine Left Atrium: Comparison Between 8 mm Tip and Open Irrigation Catheters. *J Cardiovasc Electrophysiology*, Volume 19, Issue 6, June 2008, Pages: 641-644. [FullPaperOnDisk] (ARB:32-33)

**[RFJN Original: Page 57]**

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**[RFJN Original: Page 58]**

**DECLARATION OF VALER V. SECAREA, JR.**

I, Valer V. Seacrea, Jr,. declare as follows:

I am the Appellant in this case. I have provided the documents in this Motion and Request for Judicial Notice and I created the "CD" which contains the digital version of this document.

## DOCUMENTS ON CD

The Clerk's Transcripts opened in the hyperlinks of this document are scanned copies of the original Clerk's Transcript copies. The AOB and ARB documents are exact copies of the AOB and ARB Appellant filed with the court.

## TIMELINESS OF THIS MOTION

Although it would seem that this motion might be considered untimely, its completion was affected by newly discovered material, the time taken to create the digital document on CD, and my personal health, all of which were beyond my control.

Sometime after the ARB was filed, around mid-July I discovered an FDA warning letter to a physician involved in a clinical trial. This discovery was made during research entirely unrelated to any "FDA considerations." The search terms that were used simply caused the letter to be retrieved among the search results. The FDA website containing warning letters to FDCA violators was located a short time after I finished reading the

**[RFJN Original: Page 59]**

original warning letter. At first, I read these letters with only a passing interest, until one sent to a University of California address was discovered. After that, I made a concerted effort to locate more of these. But, as "interesting" as these documents were, it took some time before I recognized them for the interpretation FDA

regulations that they were. Sometime while I was "studying" the FDA warning letters, I found the DHHS OHRP warning letter collection. But, it was now the beginning of August. During this time, I made another fortuitous find, the law review cited in this motion: Medical Research Litigation And Malpractice Tort Doctrines: Courts on a Learning Curve, *4 Hous. J. Health L & Pol'y* (2003). I remember the date. It was August 4th. For my part, it was a most informative find. It was the best review I had read on the subject of the law involved this litigation. It seemed to me that it could be characterized as a framework for the "law of this case." If I had found it at an earlier time, my AOB and ARB could have benefitted considerably.[7] (I do recognize that the AOB and ARB look like they were done by one who wished he was more knowledgeable on this subject.)

**[RFJN Original: Page 60]**

This law review article and the warning letters collection changed my view of the case. Although I had been collecting documents for a Motion for Judicial Notice since before the AOB was filed, I wondered if they would be of any real value. Now I felt that the document collection in the context of the warning letters made a statement about he circumstances of this case that provided an objective context for the parties' legal arguments to be compared to.

I only had one problem. When I finally researched

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[7] Months ago, I had been "researching" law reviews on Westlaw at the Orange County Public Law Library (OCLL), but this one somehow didn't show up in the returned results.

the Points and Authorities, I found that for the documents I wanted this court to consider, to be " not reasonably subject to dispute," the court would need to independently obtain them. The good news was most of the documents of interest were located on the Internet. The bad news was I had "downloaded" most of them myself, and forgot where I had obtained many of them. I finally did locate all the "lost URLs," but that was very time consuming.

Now I was faced with another problem. The list of URLs which related to all the matters of which I wanted to ask the court to take judicial notice was very long. That meant "someone" would need to transcribe each of them from my paper motion into an Internet browser. I didn't think that would make me very popular with the individual assigned that task. So the only solution I could think of was a hyperlinked (PDF) motion - a digital document.

**[RFJN Original: Page 61]**

I made a test document and it worked about as I thought it should. Then I attempted to make it "user friendly." I wrote a WordPerfect/ Visual Basic macro to "discover" the machine configuration on which the CD was loaded and adjust to what it saw. But, after about a week of effort, I found "an issue" with WordPerfect macros and had to abandon the effort.

Now time was getting short and I still had a great deal of writing to do. What you see before you is what I was able to produce.

My health also suffered during this time. Just before the ARB was due I became ill and needed

antibiotics. (Attachment 1-A) The ARB suffered because of that illness. I apparently waited too long to seek medical help, so the symptoms had become somewhat debilitating. Moreover, I had only outlined the Reply brief text, was still researching and still had significant work to do.

When I recovered, I reviewed the filed ARB and saw that it had truly suffered. That eventually sent me to the ER with chest palpitations. (Yes, really.) However, the ER docs didn't find anything (at that moment, they cautioned). I was then asked if I was having a stressful time. I answered in the affirmative and was given some medication. The feeling of palpitation was gone about a week later. (Attachment-2)

But, just when I thought I could devote myself to" tying up loose ends," I once again became ill after again waiting a little to long to seek

**[RFJN Original: Page 62]**

medical help (Attachment 1-B), and once again it took some time to fully recover.

Since the beginning of this litigation, I've wanted to understand it in terms of some "common sense" principles -- if they could be found. After reading the "Medical Research Litigation And Malpractice Tort Doctrines: Courts on a Learning Curve" law review, and more FDA and DHHS warning letters that I ever could have imagined I would, I think I'm beginning to understand the situation. I hope it's not too late.

This motion is submitted with the best information relative to this case that I could find, given my

circumstances and the time needed to accomplish the task. I therefore ask the court to consider it on its merits, notwithstanding its "eleventh-hour" submission.

I declare under penalty of perjury pursuant to the laws of the State of California that the foregoing is true and correct.

Dated: 22 August 2008

Respectfully submitted,

/ Original Signed /

Valer V. Secarea, Jr
Appellant and Plaintiff
in Propria Persona

(Note: the Attachments, which are copies of medical bills, including a trip to the Emergency room are omitted from this reproduction.)

**Transcribed report Excerpts:**

**Office for Protection from Research Risks (OPRR)**
**Division of Human Subject Protections**
**United States Dept. of Health and Human Services**

**Evaluation of Human Subject Protections**
**in Schizophrenia Research Conducted by the**
**University of California at Los Angeles**
**11 May 1994**

**Attachment M,**
**Response from Complaint #1: pp. 20-22**

**Attachment L,**
**Institutional Responses**

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This case again demonstrates that an institution like UCLA should not be charged with investigating itself. We hope that Congress recognizes that an incestuous network of shared interests exists when NIH conducts investigations of its own good friends, academic peers, grantees, co-authors and past employees. The climate for an objective. investigation it fatally compromised by an intricate web of existing relationships.

In this case,.the research community usurped the human rights of the subjects, then used them as if they were laboratory animals without their consent. Then, OPRR. continued to act as if the subjects. were invisible, with no voice. OPRR perpetuated the institutional disregard for a vulnerable patient population. In this investigation, the subjects: were not treated with the respect due any human being, particularly vulnerable human beings.

UCLA'S PATTERN OF CONDUCT:

UCLA. demonstrated a pattern of misconduct that violated applicable state and federal laws and federal assurances. The research conduct also involved practices that we believe seriously deviated from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. Below is a brief summary of some of the issues.

1) Experimentation without legally valid informed consent

under 45 CFR 46 and California state law.

2) Violated California state law by blocking access to patient records for three years. Violated assurances to DHHS by. violating-California state law. Refused to make records available et the request of OPRR, but only did so after the State of California issued an administrative legal ruling.

3) Requested permission from our family to release personal and confidential records to the press, while blocking access to those same records by the patient and/or his doctor. This action constituted unethical conduct by psychiatrists.

4) Blacked out Access to portions of a brain MRI protocol.

5) Blocked access to patient-records by the county of Los Angeles authorities, acting on behalf of the state of California. Violated assurances made to DHHS.

6) Excluded African-Americans from participation in this research in violation of the Civil Rights Act. Violated assurances made to DHHS. After investigation by the DHHS Office of Civil Rights, UCLA offered to admit African-Americans.

7) Recruited patients from county hospitals without the permission of the county hospital IRB's of the county hospital IRB's. The Director of Mental Health. of the County of Los Angeles was not aware of this practice.

8) Provided patients with a brochure that stated they would receive the optimal dose of medication when the protocol stated that the dose would be standardized at 12.5 mg. biweekly:

9) [REDACTED: FOIA Exemption (b)(6)]

10) Maintained patients on standardized doses when patients were responding adversely to the and the dosage, contraindicating, assertions made to OPRR by UCLA.

11) Ensured that patients would have severe or extremely severe relapses, with a prospective research design that the researchers considered an improvement over other research that intervened in the early stages of decompensation/relapse.

12) Used white-outs, alterations and obliterations and did not voluntarily explain the use of white-outs, alterations and obliterations.

13) Did not test for TD in accordance with the 1979 APA Task Force on TD, requiring testing every 3-6 months.

14) Did not inform patients at the onset of TD. Did not treat patients in an effort to minimize TD.

15) UCLA continues to release false and misleading information to the media and the public.

Our experience has led us to a number of specific conclusions about ways the system can be improved.

a) The Office of Protection from Research Risks should be an entity entirely outside the research establishment.

b) Some experts who consult for OPRR should not be a part of the research establishment. Such relationships lead to subtle and not-so-subtle conflicts of interest. There are many experts across the country whose livelihood does not depend on NIH grants.

c) There should be an active public mechanism that permits patient rights advocates across the country to participate in the process of monitoring research activity.

d) Institutions should not investigate themselves. They have an overriding conflict of interest to minimize the damage and withhold critical information from oversight offices.

e) There id a clear and dramatic need for a National IRB.

f) The laws have to provide for prompt and strong sanctions. For example, this research should have been shut down immediately when it was discovered that no legally valid written informed consent existed. A decade of unlawful research is quite enough.

**[OPRR Original: Attachment M, Page 22]**

We know that there are many fine researchers and many excellent IRB's. But this case clearly demonstrates that a major institution, with all the funds and staff to conduct research ethiCally, has overlooked fundamental concern for the welfare of subjects.

However, the problems in evidence in this research may be also occurring at other institutions. Correction of these-problems will be: difficult unless there is a new national legislative mechanism designed to make major improvements in the system.

The sad truth is that subject/patients are currently not protected in any substantive way by any office of the government

**[OPRR Original: Attachment L, Page 1]**

Attachment L
Institutional Response

The Office for Protection from Research Risks (OPRR) forwarded this report to the University of California Los Angeles on February 9, 1994. The institution's statement of response is presented here as Attachment L.

> NOTE: At the advice of the Office of the General Counsel, certain material has been withheld from Attachment L in order to respect the privacy and confidentiality interests of affected individuals.

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**"Records Falsified"**
**The Orange County Register**
**Friday, September 26, 2008:**
**Medical Records Falsification at UCI**
**(University of California at Irvine)**

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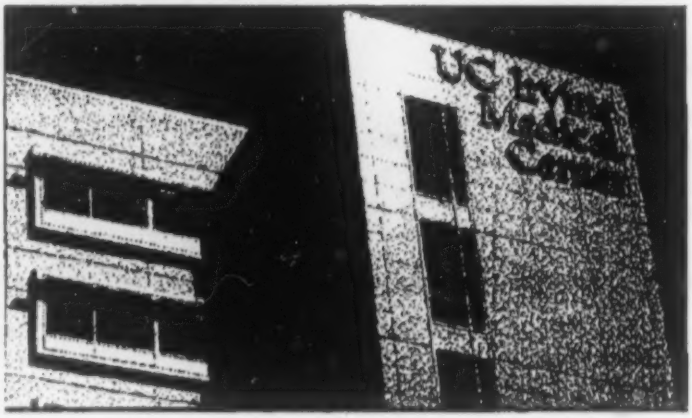
# Records Falsified

## UCI says it stopped the practice, but problem with surgical forms imperils Medicare funding.

Medicare officials have threatened to pull funding from UCI Medical Center after investigators found doctors had faked records of surgical procedures.

U C I officials admit anesthesiologists filled out records in advance of surgeries but say that has stopped. They say no patients were harmed.



Inspectors found a record of a completed surgery of a patient still on the operating table at the time of their visit. Another record, which described the patient as "stable" during surgery, was filled out three months before the operation.

Regulators said the findings "resulted in the hospital's inability to provide quality health care in a safe manner."

It's the latest in a series of scandals for the hospital, which serves thousands of the county's neediest, along with offering a trauma center, burn unit and other noted facilities.

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**Annotated excerpts from the deposition of defendant and respondent David A. Cesario, M.D., re: the medical device experimentation and physician training to which decedent Nadine Secarea was surreptitiously subjected.**

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## A. Dr. Cesario explains his student status

To start, Dr. Cesario describes his status at the time of decedent Nadine Secarea's surgery as a "trainee" Note that Dr. Swerdlow told this Petitioner that Dr. Cesario had covertly "done the burn" (the actual ablation) on Nadine , as a training exercise,[1] even though Nadine had hired Drs. Swerdlow and Shivkumar to personally perform the procedure. [2]

**[DCD [3] 10:22-11:2]**

MR. JAMES:[4] And what is an assistant fellow?

DR. CESARIO: The fellow -- a fellow is a trainee,

---

[1] Petition Appendix B-107 (SAC: Training Dr. Cesario at the Expense of Nadine's Life) See also Petition Appendix B-213 (Declaration of Valer V. Secarea, Jr., ¶¶50-53).

[2] Petition Appendix B-65 - B-72 (SAC: Nadine Selects Her Surgical Team) See also Petition Appendix B-200 (Declaration of Valer V. Secarea, Jr., ¶¶ 6-29).

[3] Reference to deposition page and line numbers are preceded by "DCD." i.e. DCD <page number>:< line number>; SAC signifies the Second Amended Complaint, this appendix.

[4] Deposition participants are identified: Fredrick James, attorney for ER physicians and Bennett Combs, attorney for temperature probe manufacturer, Vital Signs, Inc. (not parties to the appeal), Patricia Ellyatt is Dr. Cesario's attorney, and Thomas Rockett, III is this Petitioner's trial attorney. Defendant and respondent David Cesario, M.D. was the student "ghost surgeon" who performed part of the surgery on Nadine.

in my case a trainee in cardiac electrophysiology with -- I guess, sort of an apprentice in learning to do procedures, doing extra training after your general cardiology training in a subspecialty.

## B. Dr. Ceasario describes his knowledge of temperature probes

During questioning by Mr. Combs, Dr. Cesario describes the extent of his knowledge of temperature probes. But, given that Dr. Cesario published the application of the probe at issue in this case was research intended to extend generalized knowledge,[5] missing from his testimony is any explanation of how this training informed him that this new and untested use of the device was either safe or effective.. In fact, as will be seen -- as the matter was briefed to the California Courts, -- it wasn't.

**[DCD 82:4-22]**

MR. COMBS: Is this a -- is this taught in medical school to use it to try to detect a rise in core temperature during a catheter ablation?

DR. CESARIO: I don't recall a specific lecture in

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[5] Petition Appendix B-243 (Cesario D, Shivkumar K, Valderrabano M, Wiener I, Swerdlow C. Esophageal temperature monitoring during left atrial catheter ablation for atrial fibrillation. *J Am Coll Cardiol* 2005; 45 Suppl A:114A.) See also, Petition Appendix B-247 (*J Am Coll of Cardiol* Vol 45, No. 11, Suppl B, ACC 2005 Annual Session Highlights. June 7, 2005:30B-2B)

medical school on that topic, no, sir.

MR. COMBS: When was the first time that you were exposed to this use of the temperature probe?

DR. CESARIO: A During my clinical cardiac electrophysiology class.

MR. COMBS: And how long was that prior to Mrs. Secarea's procedure?

DR. CESARIO: It was a one-year fellowship from October of 2003 until October of 2004.

MR. COMBS: So it was during this fellowship that you learned of this application of the temperature probe?

DR. CESARIO: Yes, sir.

### C. The failed temperature probe study was based on supposition and speculation -- not science

One of the basic factual allegations of this litigation is that the Respondent Researchers in this case had no scientific basis for using the temperature probe at issue, as they did, When, asked directly about the temperature monitoring study that Nadine was subjected to, Dr. Cesario appears to admit that no thought had been put into the enterprise. The Respondent Researchers simply

"hoped" it would work.

**[DCD.85:11-24]**

> MR. ROCKETT: When you insert the probe, when you used the probe in this procedure, were you looking to measure body temperature, core body temperature in relationship to the ablation?
>
> DR. CESARIO: Yes, sir.
>
> MR. ROCKETT: Okay. Now, if you are ablating near the esophagus, isn't there a focal component to the measurement of temperature? Because you are not really getting core temperature, you are getting core temperature in relation to the ablation.
>
> DR. CESARIO: That was our hope.
>
> MR. ROCKETT: That was your hope. Okay. All right. Thank you. I have nothing further.

Note that the published abstract of this research, said as much, to wit:

> "We *hypothesized* that monitoring of ESO temperature (T) may detect early T rises to prevent ESO injury." [6] (Italics added.)

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[6] Cesario, et. al. op. cit. Petition Appendix B-245.

But, as is now known, that "hypothesis" was wrong. When scientific data regarding temperature measurement in the esophagus during cardiac catheter ablation became available, the conclusion was:

> ...luminal temperature measurements clearly underestimate the amount of thermal insult to the esophageal wall during ablation. [7]

Indeed it was just such a "technical failure" that this Petitioner-Plaintiff expressed in the Second Amended Complaint, [8] years before scientific data confirmed it, to wit:

> 175. But, as Plaintiff would eventually come to understand from Drs. Swerdlow and Shivkumar and the scientific and medical literature, it is a matter of speculation and conjecture as to whether the abrupt temperature rise condition that was employed in the experimental procedure to which NADINE was surreptitiously subjected is a true indicator of the conditions precedent to thermal injury to the esophagus.
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> 176. The obvious consequence of such a

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[7] Petition Appendix B-403 (Excerpt from Appellant's Reply Brief, pp. 32-34, Section IV: Expert Witness Ipse Dixitisms).

[8] Petition Appendix B-86 through B-99 (SAC §§ 173-202: UCLA Doctors Were Engaged in an Investigation of a Medical Device, etc.)

supposition being incorrect is that even the most precise measurement of esophageal temperature will fail to protect a patient-subject from esophageal injury, including the atrio-esophageal fistula which took NADINE's life. In other words, by the time the temperature probe indicates an increase of any amount, the RF catheter may have already "burned a hole" through the heart's left atrium posterior wall and through the esophagus.

177. Moreover, as Plaintiff understood Drs. Swerdlow and Shivkumar, it was not merely the temperature within the esophagus that they wished to monitor, it was the temperature of the esophagus wall ("esophageal lumen') directly across from the RF catheter positioned in the heart's left atrium. As an aerospace engineer, Plaintiff understood that such a precise measurement as this could require specialized sensors and instrumentation conceived for that purpose, depending on the character of the temperature profile being measured. This raised a number of technical questions for which Drs. Swerdlow and Shivkumar had no answer.

It was this knowledge that the Respondent Researchers in this case were required to obtain[9] – before they

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[9] Petition Appendix: Motion and Request for Judicial Notice in the California Court of Appeals (RFJN), specifically, B-292 (IDE is required when testing safety & effectiveness), B-293 (New Uses Require an IDE from the FDA), B-295 (Assurance of scientific

contemplated using the device as they did, on unsuspecting patients, like Nadine..

## D. The untested application of the Vital, Signs Inc. device at issue in this case.

Mr Coombs queried Dr. Cesario regarding the application of esophageal probes to catheter ablation only to hear Dr. Cesario's contradict the claims made in his published work., as follows:

**[DCD 78:11-80:7]**

> MR. COMBS: In this case you testified that the temperature probe was being used to monitor core temperature?
>
> DR. CESARIO: Yes, sir.
>
> MR. COMBS: And you also said that you watch for a rise of temperature in the esophagus?
>
> DR. CESARIO: Yes, sir.
>
> MR. COMBS: You realized that you are measuring the core temperature in the esophagus with the --
>
> DR. CESARIO: Yes, sir.

---

validity required for IDE applications).

MR. COMBS: -- temperature probe?

DR. CESARIO: Yes, sir.

MR. COMBS: So you are looking for a rise in the core temperature?

DR. CESARIO: Yes, sir.

MR. COMBS: You are not looking for -- you are not trying to

**[DCD 78]**

put it in such a position that you are trying to get a focal temperature from the catheter tip; correct?

DR. CESARIO: Correct, sir.

Note that this answer appears diametrically opposed to to what Dr. Cesario stated was the procedural protocol in the publication he co-authored., to wit:

> The T probe was positioned at the level of the 8-mm ablation tip for lesions on the posterior wall or roof, ...[10]

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[10] Cesario, et. al. *op. cit.* Petition Appendix B-245.

The experimental protocol's purposeful positioning of the probe nearest to the location of the ablation catheter would seem to indicate a desire to measure the temperature of the esophageal wall at the point where it is being heated by the ablation action.

Mr Combs continues:

> MR. COMBS: Okay. So all you are looking for is a rise in the core temperature based upon a reading from the esophagus?
>
> DR. CESARIO: Yes, sir.

Note that the publication he coauthored, Dr. Cesario states that the purpose of the study protocol was to measure *esophageal temperature*, not *core* body temperature. According to Dr. Cesario and his coauthors:

> "We hypothesized that monitoring of ESO temperature (T) may detect early T rises to prevent ESO injury." [11]

At this point, Dr. Cesario all but concedes that the application of an esophageal temperature probe to monitoring esophageal temperature during catheter ablation is beyond the design intent of the instrument.

However, Federal regulations preclude using a medical device in a manner inconsistent with its design

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[11] *Ibid.*

intent, when the object of that use is medical research, as is alleged in this litigation. In such cases, the research must be approved by the IRB (Institutional Review Board), the informed consent[12] of research subjects, such as Nadine, must be obtained, and an IDE must be obtained from the FDA. [13] [14]

Respondent Regents of the University of California admit this themselves in the University of California Contract and Grant Manual at Section 18-220, Applicability of Governmental Regulations and Policies to All Research:[15]

> The University is also obligated by law to adhere to the regulations of the Food andDrug Administration (21 CFR Parts 50 and 56) governing projects involving investigational new drugs [within the meaning of 21 U.S.C. sections 355(i) or357(d)], or investigational new devices [within the meaning of 21 U.S.C. section 360(g)].

Mr. Combs continues:

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[12] Petition Appendix B-286: For studies that are subject to the requirements of FDA regulations, the informed consent must be obtained in accordance with those regulations.

[13] Petition Appendix B-34(SAC §§ 77-78 enumerates the applicable Federal Regulations).

[14] Petition Appendix: op. cit. RFJN, B-292, B-293, B-295.

[15] Petition Appendix B-47.

MR. COMBS: To your knowledge this is what the temperature probe is designed for?

DR. CESARIO: No, sir. It is designed to monitor core temperature and we thought it would be an additional benefit to avoid any rises in the core temperature as related to the ablating the esophagus.[16]

MR. COMBS: You realize you are monitoring core temperature?

DR. CESARIO: Yes, sir.

MR. COMBS: So you are looking for a rise in core temperature?

DR. CESARIO: Yes, sir.

MR. COMBS: And that's what the stethoscope or the temperature probe is designed to monitor?

DR. CESARIO: Yes, sir.

MR. COMBS: Okay. And so what was -- did you feel you were using it for an off-label use? [17]

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[16] Petition Appendix B-300 (RFJN: "Standard of care" no excuse for not obtaining IDE).

[17] Petition Appendix B-319 (RFJN: IX Off Label Prescribing).

DR. CESARIO: We were using it for the on-label use of monitoring core temperature and we wanted to give an

**[DCD 79]**

additional level of safety by using it to tell us of any rise in temperature in the esophagus.[18]

MR. COMBS: Okay. But all you were doing was using it to monitor a rise in core temperature and that was what the temperature probe was designed for to your knowledge; right?

DR. CESARIO: Yes, sir.

It is noteworthy that, more than once, Dr. Cesario states this use of a temperature probe is somehow an intended use,[19] even though the use in question was published as research[20] and reported as an ultimate failure,

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[18] At the time of Nadine's procedure, and today, the "additional level of safety" supposed by Dr. Cesario could not be technically achieved. In 2008, research demonstrated that the use of a temperature probe as was applied in Nadine's procedure could not perform the measurement task the Respondent Researchers in this case had envisioned; Expert Witness Ipse Dixitisms, op. cit. Petition Appendix B-403.

[19] Petition Appendix B-?.

[20] Petition Appendix B-99 (SAC §§ 203-211: Publication of "Less Than Entirely True"Research Results); Cesario, et. al., op. cit.

allegedly, by Dr Shivkumar.[21]

In sum, it appears that Dr. Cesario's view equates the experimental study he and his coauthors published and presented to the medical community as somehow being an "intended use" of the esophageal temperature probe at issue in this case.

## E. Publication and presentation of the temperature probe study at issue in this case

Dr. Cesario now speaks to the publication and presentation of the experimental study to which he and his coauthors subjected Nadine (and other patients).

**[DCD.36:5-18]**

> MR. ROCKETT: So as of the time of the procedure, if I'm understanding you correctly, you did not understand it to be a part of any IRB protocol; correct? [22]
>
> DR. CESARIO: Other than standard retrospective analysis after it, but, yes, sir.

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Petition Appendix B-243; See also, ACC 2005 Annual Session Highlighlights, op. cit. Petition Appendix B-247.

[21] Petition Appendix B-372.

[22] See Petition Appendix B-32 (SAC §§ 72-88: UCLA Doctors Were Engaged in an Investigation of a Medical Device).

Note that a foundational element of the allegations of surreptitious medical experimentation in this litigation is that the research in question is entirely regulated by Federal law.[23]

Mr, Rockett continues the questioning:

> MR ROCKETT: Now, when you speak of the retrospective analysis, I'm unsure what that means, so I'm going to probe that a little bit with your indulgence, please. Do you know whether retrospectively or after the fact Mrs. Secarea's case, if you will, became subject of any IRB protocol?
>
> DR. CESARIO: Dr. Swerdlow and Dr. Shivkumar and myself presented -- wrote an abstract on esophageal temperature monitoring in patients undergoing left atrial catheter ablation procedures and I believe Miss Secarea was part of that. [24]
>
> MR. ROCKETT: Okay. And to whom was that

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[23] Petition Appendix B-29 (SAC § 66: Modifications of Already Cleared or Approved Devices); Petition Appendix B-31 through B-40 (SAC §§ 69-88: FDA IDE Approval Required for Medical Device Research).

[24] Petition Appendix B-79 (SAC §§ 155-202: The Experimental Form of the Ablation Procedure Revealed); Petition Appendix B-212 through B-217 (Declaration of Valer V. Secarea, Jr., ¶¶46-62, explaining how he came to know about the medical experimentation to which Nadine was subjected).

presented?

DR. CESARIO: It was presented I believe at the American Heart Association.

MR. ROCKETT: When was that presented?

DR. CESARIO: I actually believe it was presented in 2005, I believe, but I didn't present it.

MR. ROCKETT: Who presented it?

DR. CESARIO: I believe it was either Dr. Shivkumar or Dr. Swerdlow.

Dr. Cesario goes on to describe the results of the "temperature monitoring" study

**[DCD.37:10-38:28]**

MR. ROCKETT: All right. And the actual presentation included the Secarea complication that was realized?

DR. CESRIO: I believe so.

MR. ROCKETT: All right. Have you seen the abstract in any written form?

DR. CESRIO: I had in the past, yes.

MR. ROCKETT: All right. And did it specifically reference Nadine Secarea's complication?

DR. CESRIO: No, sir, the initial abstract did not.

MR. ROCKETT: Did any abstract relative to Nadine Secarea's complication get reduced to some written form by you, Dr. Swerdlow, or Dr. Shivkumar to your knowledge?

DR. CESARIO: Not to my knowledge. I believe it was presented in a verbal form.

MR. ROCKETT: Okay. Presented by whom to whom, sir?

DR. CESARIO: Either Dr. Swerdlow or Dr. Shivkumar to the American Heart Association.

MR. ROCKETT: What is the source of your belief in that regard?

DR. CESARIO: I was told by Dr. Shivkumar.

MR. ROCKETT: What did Dr. Shivkumar tell you was verbally presented to the American Heart Association as it relates to the atrial-esophageal fistula complication realized by Mrs. Secarea?

DR. CESARIO: That they presented an abstract

on temperature monitoring in the setting of left atrial catheter ablation, and mentioned that although temperature had been monitored, in one case there was an atrial-esophageal fistula.

MR. ROCKETT: Okay. So the chronology as I understand it was, of course, the procedure occurred; correct?

DR. CESARIO: Yes, sir.

MR. ROCKETT: After the procedure occurred an abstract was presented to the American Heart Association; correct?

DR. CESARIO: Submitted, yes.

MR. ROCKETT: Okay. And thereafter that was published?

DR. CESARIO: To the best of my knowledge.

MR. ROCKETT: Okay. Was it published in any medical journal to your knowledge?

DR. CESARIO: I believe a supplement to the American Heart Association Journal or to circulation, I believe.

It should be noted that. while Dr. Cesario recounted Dr. Shivkumar's presentation of their research

study to the American Heart Association, the Second Amended Complaint as well as the summary judgment briefings document Dr. Swerdlow's presentation of this research to the American College of Cardiology 2005 Scientific Session.[25] Dr. Cesario went on to describe the intent of the esophageal temperature probe study.

**[DCD 52:24-53-17]**

> MR. ROCKETT: And in the performance of that [Nadine's] procedure, sir, did it become necessary to ablate anywhere near the esophagus?
>
> DR. CESARIO: The left atrium is very near the esophagus, so yes.
>
> MR. ROCKETT: Okay. Now, you used a probe during the procedure; correct?
>
> DR. CESARIO: A temperature probe?
>
> MR. ROCKETT: Yes, sir.
>
> DR. CESARIO: Yes, sir.
>
> MR. ROCKETT: And describe your understanding as to the function or role of the

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[25] Cesario, et. al., op. cit. Petition Appendix B-243 See also, ACC 2005 Annual Session Highlights, op. cit. Petition Appendix B-247.

> temperature probe in the performance of the procedure.
>
> DR. CESARIO: It's used for two things. One, it helps the anesthesiologist monitor the patient's core temperature during the procedure; and, secondly, we're using it to help us note if there was any rise in esophageal temperature, at which point we would come off the ablation.

Note that, notwithstanding their published claim that the ablation is "stopped" for an abrupt rise in esophageal temperature of 0.5° C[26], Dr. Swerdlow explained that:

> There are no published (or to the best of my knowledge) unpublished esophageal-temperature data on which to base decisions about termination of radiofrequency energy delivery during left atrial ablation.[27]

Mr. Rockett continues the questioning:

**[DCD 72:16-74:11]**

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[26] Cesario, et. al., op. cit. Petition Appendix B-245.

[27] Petition Appendix B-90 (SAC §§ 182-183) See also Petition Appendix B-235 (12 October 2004 email from Dr. Swerdlow to Valer Secarea in response to Valer's inquiry about the temperature probe study).

MR. ROCKETT: Do you independently recall Mrs. Secarea as a patient?

DR. CESARIO: Yes, sir, just the brief meetings I had with her.

MR. ROCKETT: And do you recall Mr. Secarea?

DR. CESARIO: Yes, sir.

MR. ROCKETT: And that's the gentleman over my left shoulder here. Do you remember now that you've had a chance to see him today the contents of any dialogue you may have had with him at any time?

**[DCD 73]**

DR. CESARIO: I don't remember specifics, no, sir.

MR. ROCKETT: Do you remember anything generally?

DR. CESARIO: I believe I was introduced to him and his wife before the procedure by Dr. Swerdlow. I believe that I saw him when I checked on her that evening after the procedure and then the day of the discharge.

MR. ROCKETT: Doctor, was the probe during

th e procedure positioned under the right --

MR. SECAREA: R.F.

MR. ROCKETT: -- under the R.F. ablation catheter?

MR. COMBS: Under the R.F., in other words, physically touching?

DR. CESARIO: You mean the esophageal temperature probe?

MR. ROCKETT: Yes.

DR. CEARIO: No, sir, it was not.

MR. COMBS: Is your question that it was touching it or --

MR. SECAREA: Obviously, there were complications in the esophagus. So as they were coming down the left atrium, as it hit the esophagus and as they were watching the picture on the fluoroscope, did they try to position the probe so that it was opposite the R.F. catheter?

Dr. Cesario: Oh, no, sir.

**[DCD 74]**

MR. ROCKETT: Okay. And what -- he said that really well. The probe goes into the esophagus during the procedure; correct?

DR. CESARIO: Yes, sir.

MR. ROCKETT: And the question is: Was the catheter, the ablation catheter, placed on the outside of the esophagus but juxtapose to the probe itself so as to measure temperature?

DR. CESARIO: No, sir.

MR. ROCKETT: About that you are sure?

DR. CESARIO: I'm positive.

MR. ROCKETT: Okay.

DR. CESARIO: The goal is to avoid the esophagus. So you wouldn't want to put the two next to each other.

MR. ROCKETT: Okay. The goal is to avoid the esophagus with the catheter; correct?

DR. CESARIO: Yes, sir.

MR. ROCKETT: And why is that the goal?

DR. CESARIO: To avoid atrial-esophageal

fistula.

MR. ROCKETT: So if one touches the esophagus with the catheter, one enhances the risk of atrial-esophageal fistula; correct?

DR. CESARIO: Eventually.

MR. ROCKETT: Well, as a matter of reality?

DR. CESARIO: Sure.

However, the Second Amended Complaint alleged that avoiding the esophagus is not what the Respondent Researchers in this litigation actually did.[28] They actually ablated over it in order to test their temperature measurement theory.

Bennett Combs also queried Dr. Cesario regarding probe placement in the esophagus:

**[DCD 86:21- 89:9]**

MR. COMBS: Just a couple more. The temperature probe is followed fluoros --

DR. CESARIO: Fluoroscopy.

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[28] Petition Appendix B-103 (SAC §§ 212–218: Experimental Ablation Gratuitously Put NADINE "In Harm's Way").

MR. COMBS: -- fluoroscopy during the procedure?

DR. CESARIO: Yes, sir.

**[DCD 87]**

MR. COMBS: And can you give me your best estimate as to how close the tip of the catheter was to the end of the – the sensor end of the temperature probe during the procedure?

DR. CESARIO: I can't speculate. It would be a pure speculation.

MR. COMBS: Well, you did see -- you did observe it during the procedure; correct?

DR. CESARIO: Yes, sir, but this procedure was two years ago and I don't know how many fluoroscopic images you've seen in your life, but I've seen probably 5,000. I just don't recall.

MR. COMBS: Based on your experience in participating in these procedures, what is the closest distance that a – that the sensor end of the temperature probe would be to the tip of the catheter during any given procedure in any left atrial catheter ablation?

DR. CESARIO: In general, we try to avoid

getting too close because it would be near the esophagus but maybe 10 millimeters.

MR. COMBS: And would you always attempt to keep the temperature probe away from the esophageal wall?

DR. CESARIO: Yes, sir.

MR. COMBS: So you don't want it touching the esophageal wall; correct?

**[DCD 88]**

DR. CESARIO: It's sort of just dangling in the esophagus.

MR. COMBS: Right, and there is no intent of it to be placed against the esophageal wall; correct?

DR. CESARIO: Correct.

MR. COMBS: And ideally it remains dangling in the esophagus without touching any of the surrounding tissue?

DR. CESARIO: Yes, sir.

MR. COMBS: All right. I have nothing further. Thank you.

As noted above,[29] the temperature probe study protocol called for a careful placement of the esophageal temperature probe relative to the ablation catheter during ablations that cross over the esophagus, to wit:

> The T probe was positioned at the level of the 8-mm ablation tip for lesions on the posterior wall or roof, ...

But now, contradicting his own published work, Dr. Cesario testifies that such purposeful placement is not necessary. However, if the probe is simply "dangling," as Dr. Cesario now claims, it should be intuitive that a multitude of measurement errors could be expected, making any "measurement" so obtained worthless -- even lethal to the patient.[30]

**F. The Respondent Researchers in his case refused to come to treat the emergency condition they caused Nadine -- all but abandoning her to her fate**

Later in the session Dr. Cesario describes how the defendant physicians ("Respondent Researchers") in this case refused to come to her aid when Nadine began to suffer

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[29] Petition Appendix B-364

[30] The Experimental Form of the Ablation Procedure Revealed, op cit. Petition Appendix B-79; Expert Witness Ipse Dixitisms, op cit. Petition Appendix B-403

the complications of the experimentation she was covertly subjected to -- eventually killing her.

**[DCD 59:13-74:25]**

MR. ROCKETT: And the information imparted to you in that regard came from Swerdlow to the effect that she had some effect that she had some sort of neurologic deficit and that caused her hospitalization; correct?

DR. CESARIO: Yes, sir.

MR. ROCKETT: Were you informed of anything other than a neurological component of her state resulting in her hospitalization at that time?

**[DCD 60]**

DR. CESARIO: Not at that time.

MR. ROCKETT: You were initially of the mind -- strike that. You were immediately of the mind when you learned about her neurological status that atrial-esophageal fistula ought to be considered an explanation for her neurological status; true?

DR. CESARIO: I was concerned, yes, sir.

MR. ROCKETT: Okay. Did you express that

concern immediately to Dr. Swerdlow?

DR. CESARIO: Yes, sir, immediately.

MR. ROCKETT: And it was your understanding that Swerdlow had multiple conversations with representatives at Irvine Medical Center relative to that; correct?

DR. CESARIO: That was my understanding.

MR. ROCKETT: And it was your understanding that Swerdlow caused a publication to be communicated to Irvine Medical Center relative to atrial-esophageal fistula as a complication of the prior procedure; correct?

DR. CESARIO: That's what I was told, sir.

MR. ROCKETT: He told you that?

DR. CESARIO: Yes, sir.

MR. ROCKETT: All right. Did he tell you that he spoke with anyone at Irvine to tell them of the complication?

DR. CESARIO: Of the possibility of that complication?

MR. ROCKETT: Yes, sir.

DR. CESARIO: Yes, sir.

MR. ROCKETT: And what did he specifically tell you in that regard?

DR. CESARIO: He said that he called down there and spoke to a physician and mentioned the circulation article and ask that it be placed on the chart.

MR. ROCKETT: Okay. And did he tell you that he made any treatment suggestions to anyone at Irvine Medical Center?

DR. CESARIO: I was told that he suggested that it be evaluated for atrial-esophageal fistula either with a CT or a video esophagram and I don't recall which.

MR. ROCKETT: Okay. So he suggested a diagnostic workup for A.E.F. as you understood it; correct?

DR. CESARIO: Yes, sir.

MR. ROCKETT: And did he ever inform you that he suggested a therapeutic response to the A.E.F. if it was, in fact, diagnosed?

DR. CESARIO: We had talked about transferring the patient to UCLA for emergency surgery.

MR. ROCKETT: And that never materialized simply because Irvine informed Dr. Swerdlow that their opinion was the patient was unstable; correct?

DR. CESARIO: To the best of my knowledge.

MR. ROCKETT: And it was your understanding that it was Irvine's assessment that the patient was unstable;

**[DCD 62]**

correct?

DR. CESARIO: That's to the best of my knowledge.

MR. ROCKETT: All right. And you were never told by Dr. Swerdlow that he had more clinical information upon which to conclude she was unstable for transfer; correct?

DR. CESARIO: Correct.

MR. ROCKETT: All right. You mentioned two studies, the CAT scan and the other one is an esophageal --

DR. CESARIO: Video esophagram.

MR. ROCKETT: Is that a study with which you are familiar?

DR. CESAIO: I have never conducted a study.

MR. ROCKETT: Had you -- strike that. Did you at the time of her hospitalization have any awareness as to the study's effectiveness in diagnosing atrial-esophageal fistula?

DR. CESARIO: I went and talked to the radiologist at UCLA to ask what would be the most appropriate study. I was told the CT scan or the video esophagram.

MR. ROCKETT: Either/or?

DR. CESARIO: Either/or.

MR. ROCKETT: Did he quantify the effectiveness of either study in making the diagnosis?

DR. CESARIO: Not to the best of my recollection.

MR. ROCKETT: Irrespective of the performance of the study, the neurological presentation led you as a fellow to

conclude that atrial-esophageal fistula ought to be among the differential diagnosis; true?

DR. CESARIO: Yes, sir.

MR. ROCKETT: All right. And Swerdlow shared that as far as you know?

DR. CESARIO: As far as I know.

MR. ROCKETT: Were there any other things contemplated by you or conveyed to you by Swerdlow as being contemplated by the differential diagnosis in the patient?

DR. CESARIO: Just stroke.

MR. ROCKETT: Okay. Now, when you learned of her hospitalization, sir, did you have any knowledge as to how long she had been in the hospital before Swerdlow was contacted?

DR. CESARIO: No, sir.

MR. ROCKETT: And do you know whether it was the hospital who was first to contact Swerdlow or whether it was someone else such as Mr. Secarea in that regard?

DR. CESARIO: I'm unaware of -- as soon as Dr. Swerdlow told me about it, I suggested the atrial-esophageal fistula.

MR. ROCKETT: That instantly came to mind; correct?

DR. CESARIO: I don't know about instantly, but I made a differential diagnosis soon after.

MR. ROCKETT: High on the list?

DR. CESARIO: At least there was concern.

**[DCD 64]**

MR. ROCKETT: Well, the only things that you thought ought to be worked up diagnostically were stroke and atrial-esophageal fistula; correct?

DR. CESARIO: I don't know if they are the only things, but those are my two greatest concerns of the --

MR. ROCKETT: Fair enough. Thank you.

Do you know, sir, at the time when you first became aware of her subsequent hospitalization whether she had coded?

DR. CESARIO: I don't know, no.

MR. ROCKETT: Was it ever communicated to you that a code blue was called with respect to her?

DR. CESARIO: No, sir.

MR. ROCKETT: So am I the first one to ever mention that to you?

DR. CESARIO: Yes, sir.

MR. ROCKETT: Okay. So you have no idea as to what the chronology of her admission was at Irvine Medical other than the fact that she was admitted with neurological sequela; correct?

DR. CESARIO: Yes, sir. As soon as I heard that, I mentioned it to Dr. Swerdlow.

MR. ROCKETT: Okay. And you did the things that you told us earlier you did; correct?

DR. CESARIO: Yes, sir.

**[DCD 65]**

MR. ROCKETT: You spoke with someone who might be able to perform the surgery; correct?

DR. CESARIO: Yes.

MR. ROCKETT: You made efforts to secure an ICU bed?

DR. CESARIO: Yes, sir.

MR. ROCKETT: And that was your desire to achieve those things?

DR. CRSARIO: Yes, sir.

MR. ROCKETT: And the impediment to achieving those things was a representation by Irvine Medical as to the instability for transfer; correct?

DR. CESARIO: To the best of my recollection.

MR. ROCKETT: Okay. Do you recall anything else other than that being imparted to you?

DR. CESARIO: No, sir.

MR. ROCKETT: And you believe that you may have had one conversation with the doctor designated as the attending for her, but you can't specifically recall whether it was Dr. Schwartz; true?

DR. CESARIO: True.

MR. ROCKETT: And are you sure you spoke with someone and you just don't know what the name is or are you just not sure whether you spoke with anyone?

DR. CESARIO: I'm sure I spoke with someone.

MR. ROCKETT: Okay. And you spoke with someone you believe to

**[DCD 66]**

be a doctor?

DR. CESARIO: Yes, sir.

MR. ROCKETT: And you communicated your concerns about atrial-esophageal fistula?

DR. CESARIO: Yes, sir.

MR. ROCKETT: All right. Do you recall having any other conversation with anyone at Irvine Medical relative to Mrs. Secarea?

DR. CESARIO: No, sir. Dr. Swerdlow had those conversations.

MR. ROCKETT: And he was keeping you informed as far as you knew as to her progress

and his dialogue with her by medical in that regard; correct?

DR. CESARIO: Yes, sir.

MR. ROCKETT: While Dr. Shivkumar was on vacation, did you make effort to communicate with him -- I don't know if he was on vacation. He was out of the country. Did you make efforts, sir, to communicate with him relative to Mrs. Secarea's care?

DR. CESARIO: Yes, sir. I called him every day.

MR. ROCKETT: Okay. And why did you do that?

DR. CESARIO: Because I was concerned.

MR. ROCKETT: Okay. And did he communicate to you what he thought ought to be done as it relates to Mrs. Secarea?

DR. CESARIO: Yes, sir.

MR. ROCKETT: What did he communicate to you in that respect,

**[DCD 67]**

sir?

DR. CESARIO: That we should try to transfer her to UCLA, which we had already initiated the process.

MR. ROCKETT: Okay. And did he communicate anything else in terms of her diagnostic or therapeutic workup?

DR. CESARIO: No, sir, not other than what had already been mentioned.

MR. ROCKETT: Do you know whether any doctor, including yourself, made any effort to see the patient at Irvine Medical?

DR. CESARIO: I suggested to Dr. Swerdlow that we should drive down and go evaluate her, and he did not think we should.

MR. ROCKETT: And did he give you his reason for not doing so?

DR. CESARIO: Other than he thought that the physicians down there were caring for her and we should just assist with the transfer he said.

MR. ROCKETT: When did that conversation occur between you and Dr. Swerdlow?

DR. CESARIO: I believe it was on the day that he informed me.

MR. ROCKETT: So the same day that you first learned of the condition, you contemplated that excursion to Irvine; correct?

DR. CESARIO: Yes. I wanted to be assistant in any way possible.

MR. ROCKETT: You did everything you could to help the

**[DCD 68]**

patient?

DR. CESARIO: I wanted to.

MR. ROCKETT: Okay. Have you had any dialogue, sir, with Shelly Quartz since the time the patient was discharged?

DR. CESARIO: Shelly Quartz?

MR. ROCKETT: I can't read my own writing.

MS. ELLYATT: Shelly Coty.

DR. CESARIO: Coty.

MR. ROCKETT: Pardon me. Shelly Coty.

DR. CESARIO: Many times. Shelly Coty is my

nurse practitioner.

MR. ROCKETT: I mean, relative to the care of Mrs. Secarea.

DR. CESARIO: I believe I informed her of what happened with the Irvine hospitalization and that we were trying to transfer her and the ultimate outcome.

MR. ROCKETT: All right. And you earlier testified that you participated in the patient's discharge from UCLA; correct?

DR. CESARIO: Yes, sir.

MR. ROCKETT: And Miss Coty was there at the time?

DR. CESARIO: Yes, sir.

MR. ROCKETT: And she actually signed her discharge note; correct?

DR. CESARIO: Yes, sir.

MR. ROCKETT: What was your understanding as to the discharge

**[DCD 69]**

instructions given to the Secareas?

DR. CESARIO: That she was to discharge home, to call us if there was any complications or concerns, and that they were supposed to follow up, I believe, in one month.

MR. ROCKETT: Okay. And was it imparted to the Secareas what you would consider to be a manifestation of a complication relative to the procedure? In other words, what sorts of things might they look at and be concerned about?

DR. CESARIO: I don't recall the exact one but, yes, the standard.

MR. ROCKETT: And what is it that you would say as a matter of standard in giving such instructions?

DR. CESARIO: Watch for signs of bleeding, infection, which would include fevers, chills, sweats, any neurologic symptoms, any swelling in the areas of the puncture site, you should call immediately.

MR. ROCKETT: And you wanted a call immediately if any of those things arose because they could be serious problems?

DR. CESARIO: Yes, sir.

MR. ROCKETT: And upon receiving information of that nature from the patient following a procedure of this type, you would immediately instruct the patient go to the hospital; correct?

**[DCD 70]**

DR. CESARIO: Yes.

MR. ROCKETT: All right. Would you instruct the patient to go to UCLA or --

DR. CESARIO: To the closest hospital near them and then be transferred to UCLA.

MR. ROCKETT: You wouldn't tell the patient to wait and see what happens after receiving information of that nature, would you?

DR. CESARIO: No. Me personally, sir, no.

Note that when Nadine contacted Dr. Swerdlow to report her sudden neurological symptoms, but Dr. Swerdlow's response was to "wait and see.." [31] Shortly thereafter, Nadine collapsed and was taken emergently to Irvine Hospital and medical Center, where, as Dr. Cesario

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[31] Petition Appendix B-209 (Declaration of Valer V. Secarea, Jr., ¶¶37-41, describing the conversation he and Nadine had with Dr. Swerdlow regarding Nadine's sudden neurological symptoms).

testified , above,[32] that Dr. Swerdlow refused to treat her for the injury he had caused.

Mr. Rockett continues the questioning:

> MR. ROCKETT: In any of your discussions with Swerdlow or the doctor at Irvine Medical, did the subject of prophylactically stinting the esophagus ever come up?
>
> DR. CESARIO: I don't recall.
>
> MR. ROCKETT: Did the subject of therapeutically stinting the esophagus ever come up?
>
> DR. CESARIO: I don't know.
>
> MR. ROCKETT: Are you aware of stinting as being an appropriate medical response to an atrial-esophageal fistula?
>
> DR. CESARIO: In this setting usually it's a surgical emergency.
>
> MR. ROCKETT: I'm sorry. What do you mean?
>
> DR. CESARIO: In the setting of post-catheter ablation in someone having strokes, usually it's an open surgical procedure to the best of my

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[32] Petition Appendix B-394.

knowledge.

**[DCD 71]**

MR. ROCKETT: I'm not understanding what you mean in terms of --

DR. CESARIO: In the setting of a patient who's had strokes, has had a left atrial catheter ablation, and has possible recurring emboli, to the best of my knowledge, those patients are managed with an open surgical procedure.

MR. ROCKETT: Okay. Did you ever discuss with Dr. Swerdlow the propriety of stinting the patient?

DR. CESARIO: Not to my recollection.

Note: after Nadine was taken to the ICU at Irvine Regional Hospital and Medical Center, Dr. Swerdlow explained to Valer that Nadine 's esophageal injury could be sealed with a stent (not "stint"), which would in turn allow the injury to heal.[33]

MR. ROCKETT: And did you ever discuss with Dr. Swerdlow other than transferring any therapeutic options available to the patient if, in

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[33] Petition Appendix B-212 (Declaration of Valer V. Secarea, Jr., ¶49, describing Dr. Swerdlow's explanation of how he intended to treat Nadine's esophageal injury).

fact, she had an A.E.F.?

DR. CESARIO: Surgical intervention, but other than that, no.

MR. ROCKETT: To do what?

DR. CESARIO: To do an open surgical procedure to try to close the esophageal fistula.

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**Excerpt from Appellant's Reply Brief, pp. 32-34, Section IV: Expert Witness Ipse Dixitisms**

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## A. Dr. Andrea Natale (2.CT.558-556)

### 4. The temperature probe experiment

Dr. Natale states, without any line of reasoning leading to the ultimate conclusion that the atrio-esophageal fistula complication was somehow inevitable. He states that there is no way to avoid an atrio-esophageal fistula (2.CT.564:8-9) However, if that is so, he never explains why the Respondent Researchers found it necessary to ablate into Nadine's esophagus, while they "measured the temperature" there, for no apparent therapeutic reason. (1.CT.77:17-19; 1.CT.127-129:10-11/SAC §§212-218; Pleadings define the issues, supra, III.B.1:ARB:6)

Next Dr. Natale embarks on a dissertation about use of temperature probes. (2.CT.564:8-18) But, he never addressed their use in the context of the issues framed by the Second Amended Complaint. (1.CT.113-129; SAC §§155-218; also There is a triable issue as to whether the UCLA Respondents conducted medical experimentation upon Nadine, which required her informed consent, VII.D.2.d:AOB:62-64)

However in a recent research paper using animals, by Cummings, et. al. (Cummings Scientific Paper),[9] which

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[9] http://www.blackwell-synergy.com/doi/abs/10.1111/j.1540-8167.2008.01130.x

J. E. Cummings, M.D., C, D. Barrett, M.R.C.P., K. N. Litwak, D.V.M., PH.D., L. Di Biase, M.D., P. Chowdhury, M.D., S.

included Dr. Natale as co-



author, published 26 March 2008, the researchers demonstrated that a probe similar to the one at issue in this litigation cannot perform the task of accurately measuring esophageal temperature during cardiac catheter ablations. (See 1.CT.122-124/SAC §§189-199). In the Cummings Scientific Paper, the authors point out, at page 3, second column:

> First, luminal temperature measurements clearly underestimate the amount of thermal insult to the esophageal wall during ablation. Second, different catheters produce different heating patterns of the atrium and esophagus. ... Though the OIC catheters are set at lower power settings, their ability to deliver consistent power through irrigation/cooling at the tissue catheter interface produces higher esophageal tissue temperatures than the 8 mm solid tip catheters with higher power settings. Third, heating of the esophageal wall occurs much more rapidly than

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Oh, M.D., C. K. Ching, M.D., W. I. Saliba, M.D., R. A. Schweikert, M.D., J. D. Burkhardt, M.D., S. De Marco, R.V.T., L. Armaganijan, M.D., and A. Natale, M.D., Esophageal Luminal Temperature Measurement Underestimates Esophageal Tissue Temperature During Radiofrequency Ablation Within the Canine Left Atrium: Comparison Between 8 mm Tip and Open Irrigation Catheters. *J Cardiovasc Electrophysiol*, Vol. pp. 1–4)

demonstrated by the luminal temperature reading.

Measurement of the esophageal luminal temperature has several intrinsic flaws by the nature of the device used as well as by the anatomy itself. The esophagus is a flat collapsed tube-like structure with a variable diameter and wall thickness that is dependent on the peristaltic contractions of its smooth muscle. This variability, along with the differences in fat deposition in the atrial-esophageal space, contributes to the limited accuracy of the temperature probe placed in the center of the tube. Clearly, the amount of heat dispersion from the catheter tip through to the esophageal lumen depends on all these variables, as well as the

**[Appellant's Reply Brief: Page 34]**

cooling effect of the local arterial and venous bloodflow and saliva flow around and through the esophagus.

If researchers are only now, in 2008, beginning to understand the limitations of esophageal temperature probes of the kind used in the medical experiment Nadine was subjected to, then they had no such knowledge in August 2004. (Scientifically and Medically Unsound Procedures, supra, III.K:ARB:23) Under these circumstances, Dr. Natale's conclusion that this use was somehow within the "standard of care," simply has no support

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